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(54) **Expandable transluminal graft prosthesis for repair of aneurysm and method for implanting.**

(57) A transluminal grafting system for grafting a prosthesis (1,12) to the wall (2) of a lumen includes a tubular graft (1) provided with spring assemblies (12) and anchoring barbs (205). The prosthesis is mounted on an apertured tubular carrier (21) and a central control means (26) is inserted into the bore of the apertured carrier. Mooring loops (36) are attached to the prosthesis, pass through the apertures (29) of the tubular carrier, and engage the central control means. An introducer sheath covers the system for smooth insertion into a lumen. When the graft has been positioned, the central control means maintains the axial position of the prosthesis. When the introducer sheath (4) is pulled, the prosthesis is exposed and the spring assemblies return to an expanded state and anchor the graft against the internal wall of the lumen.

EP 0 539 237 A1

The invention relates to an arrangement for percutaneously positioning a graft within a lumen.

The abdominal aorta is prone to aneurysmal dilation bewteen the renal and iliac arteries, and is occasionally unable to withstand arterial pressures so that dilation tends to progress to a point where rupture is likely. Highly invasive conventional repair such as described in U.S. Patent No.3,657,744 is expensive and life threatening. The invention, however, is not limited to aortic aneurysm repair and has applications in a variety of situations in which corporeal lumen repair is required.

There are several devices already existing which are stated to be useful for the remote repair of corporeal lumens, such as described in U.S. Patent No.4,512,338, (Balko et al). The exact position of both ends of the prostheses is very important due to the proximity of vital arteries to the ends of the aneurysm, and the condition of the lumen at the points of attachment.

U.S. Patent No.4,140,126, (Choudhury), discloses another device for repairing an aneurysm.

U.S. Patent No.4,787,899, (Lazarus), describes another system for positioning a graft within a body lumen.

The report, 'Percutaneously Placed Endovascular Grafts for Aortic Aneurysms: Feasibility Study', from the Department of Diagnostic Radiology, University of Texas M.D. Anderson Cancer Center, printed in 170 Radiology 1033-37 (1989), deals with a self-expanding graft consisting of several stents connected in a chain. In the feasibility study, there is described an arrangement in which a prosthesis is pushed into a tubular outer sheath by a blunt tipped wire. When the outer sheath is removed, the wire is held tight on the proximal end of the assembly and that has the effect of expanding and/or buckling the prosthesis within the sheath. That makes withdrawal of the sheath difficult, and it also has the effect of moving the prosthesis out of alignment from its desired location.

Endovascular repair of abdominal aortic aneurysm avoids much of the morbidity and mortality associated with conventional surgery. Most patients with abdominal aortic aneurysm lack a segment of non-dilated aorta suitable for attachment of the down stream (caudal) end of a straight (single-lumen) endovascular graft. In these patients a more secure outflow is provided by attaching the two caudal ends of a bifurcated graft to the iliac arteries.

The caudal ends of bifurcated grafts cannot extend to the sites of arterial access in the groin without impairing internal iliac arterial flow, which is an important source of spinal and colonic perfusion after aortic aneurysm repair. Therefore, direct control of the caudal ends of bifurcated grafts is not possible, resulting in a tendency to kinking, twisting and displacement, all of which have complicated previous attempts to apply this approach. The devices and techniques described below provide a means of accurate, hemostatic and permanent insertion of a bifurcated graft, with provision for the prevention of correction of these potential complications.

According to the present invention, there is provided an arrangement as defined in claim 1.

The invention provides a coupling between a plurality of spring expanding assemblies that provides a relatively flexible prosthesis during insertion, a relatively rigid prosthesis after attachment, and also maintains the alignment of the springs when the prosthesis is compressed by an extrusion device applied to one end.

One embodiment of the present invention provides a flexible spring alignment and compression resistance assembly comprising a first and second spring expanding assembly each having a plurality of apertures; a plurality of retaining shafts each having a first end and a second end, the shafts having a diameter equal to or smaller than the apertures of the first and second spring expanding assemblies, the first end of each of the retaining shafts slideably inserted into one of the apertures of the first spring expanding assembly and the second end of each of the retaining shafts slideably inserted into one of the apertures of the second spring expanding assembly, a first protrusion attached to each of said first ends and a second protrusion attached to each of said second ends, the protrusions larger than the apertures of the first and the second spring expanding assemblies to prevent the protrusions from passing through the apertures.

Another embodiment provides a flexible spring alignment and compression resistance assembly comprising a first spring expanding assembly having a plurality of apertures; a second spring expanding assembly; a plurality of retaining shafts each having a first end and a second end, the shafts having a diameter equal to or smaller than the apertures of the first spring expanding assembly, the first end of each of the retaining shafts slideably inserted into one of the apertures of the first spring expanding assembly and the second end of each of the retaining shafts attached to the second spring expanding assembly, a protrusion attached to each of said first ends, the protrusions larger than the apertures in the first spring expanding assembly to prevent the protrusions from passing through the apertures.

In certain embodiments of the invention, the retaining means is an elongated member extending within the prosthesis and one or more connections are made between the elongated member and the spring(s) and/or graft of the prosthesis. It is preferable for each connection to be made to the prosthesis at a location which is well spaced from the proximal end of the member. In that way, during the removal of the sheath, the reactionary force on the said mem-

ber will be applied towards the distal end of the prosthesis, and the expansion and distortion effects mentioned above in the Gianturco reference, will consequently be avoided.

The foregoing problems are also solved and another technical advance is achieved by an illustrative transluminal arrangement for positioning a prosthesis assembly in a particular bifurcated lumen. The bifurcated lumen includes, for example, the main lumen of the aorta and the branch lumens of the common iliac arteries. An aneurysm is commonly found in the aorta just proximal the branching of the common iliac arteries. A prosthesis assembly for positioning in the aneurysm of the bifurcated lumen includes a bifurcated endovascular graft having a main body and first and second limbs extending therefrom. The assembly also includes main and branch limb spring assemblies each having a compresses state. The main bore spring assembly radially expands to substantially conform the main body of the graft to the interior wall of the aortal lumen. The ipsilateral and contralateral limb spring assemblies radially expand to conform the limbs of the graft to the interior walls of the branch lumens of the ipsilateral and contralateral iliac arteries. The transluminal arrangement comprises containers such as sheaths for containing each of the spring assemblies in a compressed state and a retainer assembly positioned in the main and ipsilateral bores of the graft for retaining the prosthesis assembly at the aneurysm in the bifurcated lumen while the main outer sleeve is withdraw from the prosthesis assembly, thereby releasing the main spring assembly from its compressed state. Branch limb retainer means attached to the ipsilateral and contralateral spring assemlies retain these spring assemblies in respective container sheaths.

The main container includes an outer sheath with a longitudinal bore wherein the prosthesis assembly is positioned. The ipsilateral and contralateral containers each include a sheath with a longitudinal bore wherein the ipsilateral and contralateral spring assemblies are positioned and contained in their compressed state.

The main retainer assembly of the transluminal arrangement comprises an elongated member having a dilator head at the distal end thereof, a main attachment assembly for temporarily attaching the main spring assembly to the elongated member and a branch limb attachment assembly for temporarily attaching the branch limb spring assembly to the elongated member. An inner catheter is positioned through the elongated member for releasing at least one of the main and ipsilateral attachment assemblies either during or after removal of the main and first sheaths. A control limb delivery catheter forms a second release assemly, which is temporarily attached to the contralateral spring assembly with an attachment suture extending therethrough for releasing the contralateral spring assembly when positioned in the contralateral common iliac artery.

The main and ipsilateral attachment assemblies each comprise attachment sutures for temporarily pulling the main and ipsilateral spring assemblies inwardly to their compressed state when the prosthesis assembly is positioned within the main sheath.

The transluminal arrangement also includes a method of positioning the prosthesis assembly at the aneurysm in the bifurcated lumen. The method includes providing cross access to the branch lumens and inserting a cross femoral wire guide between the branch access sites. The transluminal arrangement is positioned in the bifurcated lumen via the ipsitateral access site. The outer sheath is withdrawn from the prosthesis assembly and the contralateral lift is positioned with the aid of the cross femoral guide pulling the control limb delivery catheter of the transluminal arrangement. The attachment sutures are released from the prosthesis assembly when positioned at the aneurysm in the bifurcated lumen allowing the main spring assembly to radially expand and conform the graft to the aorta. The branch limb containers of the transluminal arrangement are also withdrawn from the branch spring assemblies which then radially expand the ipsilateral and contralateral limbs of the graft to the common iliac arteries so as to advantageously prevent retrograde flow of blood back to the aneurysm. Similarly, the main spring assembly conforms the cranial orifice of the main body of the graft to the wall of the aorta preventing antegrade flow of blood into the aneurysm.

Brief description of the drawings

FIG.1 is a side view of a tubular graft of an embodiment;

FIG.2 is a side view of a spring expanding assembly of the embodiment;

FIG.3 is a top cross-sectional view of a spring expanding assembly shown in FIG.2 taken along A-A;

FIG.4 is a top cross-sectional view of a spring expanding assembly shown in FIG.2 taken along B-B;

FIG.5 is a side view of alternative elbows of the spring expanding assembly of another embodiment;

FIG.6 shows a spring expanding assembly (with a barb attached) sutured to the graft;

FIG.7 is a side view of a flexible spring alignment and compression resistance assembly;

FIG.8 shows the elbow and retaining bar of the flexible spring alignment and compression resistance assembly of FIG.7;

FIGS.9-A and 9-B are longitudinal cross-sectional views of two compressed and two uncompressed spring expanding assemblies re-

spectively which are connected by the flexible spring alignment and compression resistance assembly of FIG.7;

FIG.10 is a side-view of a flexible spring alignment and compression resistance assembly and shows the retaining bar rigidly attached to one of the spring expanding assemblies;

FIG.11 is a longitudinal cross-sectional view of a tubular carrier shown with a dilator head at the distal (upstream) end;

FIG.12 is a longitudinal cross-sectional view of a "muzzle loading" apparatus;

FIG.13 is a longitudinal cross-sectional view of the proximal (downstream) end of the introducer sheath;

FIG.14 is a longitudinal cross-sectional view of the aorta and iliac arteries and shows a dilator head, introducer sheath, tubular carrier, arteriotomy, and central control means;

FIG.15 is a longitudinal cross-sectional view of the aorta and iliac arteries and shows a graft implanted in the aorta on either side of an aneurysm;

FIGS.16 and 17 are longitudinal cross-sectional views of an apertured tubular carrier showing mooring loops and central control means;

FIG.18 is a longitudinal cross-sectional view of an alternative means of graft attachment;

FIG.19 is a longitudinal cross-sectional view of an occlusive umbrella;

FIG.20 is a longitudinal cross-sectional view of the aorta and the iliac arteries showing the use of a graft in conjunction with an occlusive umbrella and a femoro-femoral graft;

FIG.21 depicts a segment of a self-expanding stent;

FIG.22 depicts a bifurcated graft;

FIG.23 depicts a carrier of an embodiment;

FIGS.24 and 25 depict alternative embodiments of a sheath with a tapered cranial external surface;

FIGS.26 and 27 depict a carrier of another embodiment;

FIG.28 depicts tubular extensions sutured to a graft of an embodiment:

FIG.29 depicts an alternative mechanism for attaching the tubular extensions to a graft;

FIG.30 depicts a single loop of suture material for applying traction to a caudal limb;

FIG.31 depicts attachment to multiple points on a caudal limb;

FIGS.32 and 33 depict catheter side ports for allowing traction to be applied at multiple points;

FIG.34 depicts tension transmitted through a short suture;

FIGS.35 and 36 depict a caudal limb control catheter of the caudal limb control system;

FIG.37 depicts a suture encircling a catheter of the contralateral lumen access guidance system;

FIG. 38 depicts access to the ipsilateral limb lumen by an insertion delivery wire;

FIG. 39 depicts a distal stent insertion device of the present invention;

FIG. 40 depicts a contralateral limb straightening device;

FIG. 41 depicts an alternative limb straightening device;

FIG. 42 is a sectioned view of a twist-preventing, double lumen catheter;

FIG. 43 depicts a partially sectioned view of a transluminal arrangement of the present invention for positioning a prosthesis assembly at a particular position in a bifurcated lumen;

FIG. 44 depicts a partially sectioned side view of ipsilateral limb spring assembly of the prosthesis assembly and stent boot of the transluminal arrangement of FIG. 43;

FIG. 45 depicts a partially sectioned side view of contralateral spring assembly of the prosthesis assembly and control limb delivery catheter of FIG. 43;

FIG. 46 depicts a partially sectioned side view of contralateral stent boot temporarily attached to control limb delivery catheter of FIG. 45;

FIG. 47 depicts a prosthesis assembly of the present invention positioned in the bifurcated lumen of the aorta and common iliac arteries extending therefrom; and

FIGs. 48 and 49 depict the method of deploying a cross femoral wire guide between femoral access sites positioned on opposite sides of the groin.

The graft 1 shown in FIG. 1 is in the form of an elongated cylindrical tube defining a longitudinal bore that is multiply crimped 3, or folded over to facilitate the compression and expansion of the graft as the diameter 5 of the graft decreases and increases. Transverse elasticity may also be achieved or enhanced through inherent properties of either the weave or constituent fibers used to construct the graft 1. The graft 1 is preferably constructed from a material such as woven multifilament polyester (such as Dacron™), which is known to be sufficiently biologically inert, non-biodegradable, and durable to permit safe insertion inside the human body. Any material with such qualities may be used, however. Polyester is also known to excite fibrous ingrowth which will secure the graft 1 to the wall of the lumen within a few months of its insertion.

The typical graft 1 is of fixed length and relatively inelastic along its longitudinal axis. A variable length graft may also be used and could be constructed by either having two pieces of graft, one inserted within the other in a telescopic arrangement, capable of being manipulated within the body, or having one continuous piece of material that is folded back on itself.

A spring within this area of the graft ensures apposition of the various layers at this level; the outer layers having a slightly smaller maximum diameter to provide a buttress against which the spring can expand in the absence of a secure arterial wall. Variability of length may also be achieved by providing elasticity along the longitudinal axis of the graft as a property of graft material or by having one or more elastic sections of such material within the main body of the graft.

The spring assembly 6 of FIG. 2 includes arms 15 which are bent to form elbows 7. Surgical barbs 10 having sharp tips 13 are attached to the arms 15 and protrude from the elbows 7. FIG. 3 is a top cross-sectional view of the spring assembly 6 of FIG. 2 taken along A-A showing six elbows 7 and associated barbs 10. FIG. 4 is a top cross-sectional view of the spring assembly 6 taken along B-B showing twelve arms 15 which extend from the six elbows 7 shown in FIGs. 2 and 3. A spring assembly 6 is typically formed from a continuous piece of fine gauge stainless steel spring wire that, if opened out, would appear in the shape of a zig-zag with multiple elbows 7. FIG. 5 shows that these elbows 7 may be simple arches 7, recurved arches 42, or apertured 60. The advantage of simple arches 7 is that the spring assembly 6 expands the longitudinal aperture of the graft 1 more evenly. The advantage of the recurved arches 42 is that they collapse more readily and are more durable. The apertured elbows 60 are used in the flexible spring alignment and compression resistance assembly. The two ends of the piece of bent wire are permanently attached end-to-end so as to form a circular structure, e.g., FIGs. 2, 3 and 4. FIG. 6 shows a portion of the spring assembly 6 with a barb 10 attached to an arm 15 of the spring assembly 6. The spring assembly 6 is sutured to the graft 1 with a non-biodegradable thread 36. The spring assembly 6 may also be constructed out of other inert metals such as titanium, or a plastic. When expanded, the spring assembly 6 is circular in shape when viewed from above, and may have a diameter, when in a relaxed state, equal to approximately twice the diameter of a lumen into which the graft 1 is to be inserted. The spring assembly 6 is typically attached to the inside of the cylindrical graft 1 at the distal (upstream) end or both ends of the graft 1 by sutures 36 of non-biodegradable material. The sutures 36 attach to the spring assembly 6 in such a way that the majority of the spring assembly 6 is covered by the graft material 1. Other embodiments may incorporate spring assemblies 6 being attached to the outside of the tubular graft 1 which would present a smoother surface to the flowing blood but has the drawback that the graft 1 would be in less intimate contact with the wall of the lumen.

The spring assembly 6 on the distal (upstream) end of the graft 1 has small surgical barbs 10 firmly attached to the spring assembly 6. The spring assembly 6 at the proximal (downstream) end of the graft may also be provided with barbs. The attachment of the barbs 10 to the graft or spring assembly 6 must be permanent and can be either welded, brazed, or coupled in a fashion that is both biologically acceptable, and yet strong enough to withstand long-term stress. These barbs 10 spread radially outward from the longitudinal axis of the graft 1, such that when the spring assembly 6 opens inside the lumen, the barb tips 13 will come into contact with and engage the wall of the blood vessel to be repaired. The barb tips 13 will become imbedded in the wall through both the driving action of the spring assembly 6 and the pressure created by the flow of blood through the graft 1. The barb tips 13 are sharp and may be curved slightly downward toward the graft 1 to provide a more secure anchor in the direction of blood flow. The barbs 10 are positioned so that they are further upstream than the elbows 7 of the distal (upstream) spring assembly 12, and are of such a size that the wall of the blood vessel is not punctured or pierced when the barb tips 13 are firmly embedded therein. Attaching the barbs 10 to the spring assembly 6 via shafts bonded to the spring assembly 6 at the middle of one of the two arms 15 extending from an elbow 7 of the spring assembly 6 permits the barb tip 13 to slightly retract or rotate when compressed for loading into the introducer sheath 4 (as best seen in FIG. 6).

Though the spring assembly 6 is typically sutured only to the ends of the graft 1, several such spring assemblies 6 may also be connected to one another for added strength. This is necessary in embodiments of the prosthesis that require the graft to resist compression during removal from the introducer 4. Some flexibility is retained by connecting the spring assemblies 6 to each other in a way that permits separation (but not overlapping or misalignment) of adjacent spring elbows 60. Fig. 7 illustrates such a flexible spring alignment and compression resistance assembly 49 and shows a first spring arm 50 and a second spring arm 52 connected via a retaining bar 54. The retaining bar 54 is constructed of fine gauge wire with a protrusion 56 at each end. FIG. 8 shows a modified elbow 60 and includes an aperture 58 provided to receive the retaining bar 54. The retaining bar 54 slides through apertures 58 provided in the modified elbows 60 of adjacent arms 50 and 52. The rigidity of the retaining bar 54 prevents overlapping during compressive loading of the prosthesis, while the protrusions 56 prevent disassociation of the joints during flexion of the graft which might otherwise disrupt the chain of springs 50 and 52. The shaft 62 of the retaining bar 54 has a diameter slightly smaller than aperture 58 and the protrusion 56 has a diameter slightly larger than the aperture 58. The slidably mounted retaining bars 54 allow arms 52 and 54 to separate but prevent arms 52 and 54 from sliding over one another.

It is desirable that the joint between the spring assemblies 6 be flexible during the introduction and relatively rigid once the graft has been implanted. As shown in FIGs. 9-A and 9-B, the joint is more flexible when the spring assemblies 64 and 66 are compressed (i.e., during insertion) and relatively rigid when the spring assemblies 64 and 66 are in an uncompressed state (i.e., after implantation). FIGs. 9-A and 9-B show a first spring assembly 64 connected to a second spring assembly 66 by a flexible spring alignment and compression resistance assembly 49. FIG. 9-A shows the spring assemblies 64 and 66 in a compressed state and FIG. 9-B shows the spring assemblies 64 and 66 in an uncompressed state. Angle α represents the maximum angle between spring assemblies 64 and 66 when the springs are in a compressed state and angle β represents the maximum angle between spring assemblies 64 and 66 when the springs are in an uncompressed state. Thus, the angle between spring assemblies 64 and 66 decreases with an increase in the transverse diameter of spring assemblies 64 and 66. The angle of flexion will be largest when spring expanding assemblies 64 and 66 are in a compressed state (diameter d_1) and the angle of flexion will be smallest when spring expanding assemblies 64 and 66 are in an uncompressed state (diameter d_2). Thus, because α is larger than β, the prosthesis becomes more rigid as its diameter increases. During insertion, the graft 1 is confined within the introducer sheath 4 and remains both narrow and flexible. After removal from the sheath 4 the graft 1 expands becoming more rigid.

The retaining bar 54 may also be non-slidably attached at one (but not both) of its ends to one of the spring expanding assemblies 51 as shown in FIG. 10.

FIG. 11 shows a tubular carrier 21 which has a dilator head 22 mounted at the distal (upstream) end. The dilator head 22 may have a distal (upstream) conical portion 75 and a proximal (downstream) cylindrical portion 74. The dilator head 22 may have a soft tipped guide-wire 68 protruding from its distal (upstream) end. The cylindrical portion 74 of the dilator 22 has a diameter d equal to the internal diameter of the introducer sheat 4.

FIG. 12 shows the assembled "muzzle loading" apparatus and includes a tubular carrier 21 with a dilator head 22 at the distal (upstream) end; dilator head lip 27; introducer sheath 4; graft 1 which is slid onto the tubular carrier 21; distal (upstream) spring assembly 12; proximal (downstream) spring assembly 31; central control means 26 which is inserted into the tubular carrier 21; distal (upstream) end 8 of the graft 1; proximal (downstream) 9 end of the graft 1; and non-biodegradable sutures 36 that permanently attach the spring assemblies 12 and 31 to the graft 1. If the outer diameter of the tubular carrier 21 is equal to the internal diameter of the introducer sheath 4, leakage of blood between the two is minimal. Alternatively, the introducer sheath 4 may be closed at its proximal (downstream) end by a small rubber seal 70 as shown in FIG. 13 which has an aperture 72 for receiving the carrier 21.

"Muzzle loading" involves inserting the graft 1, already counted on the tubular carrier 21, into the distal (upstream) end of the introducer sheath 4 before insertion of the introducer sheath 4 into the lumen. "Breech loading" involves inserting the graft 1 into the introducer sheath 4 from the proximal (downstream) end of the sheath 4, after the introducer sheath 4 has been inserted into the patient and is in position.

"Muzzle loading" has two main advantages that make it the preferred means of operation. The first advantage of "muzzle loading" over "breech loading" is the lower probability of hemorrhage. In the "breech loading" technique, the dilator 22 must be removed before the graft 1 can be inserted, leaving the introducer sheath 4 as a large conduit between the arterial circulation and the outside of the body. Any effective seal in the introducer sheath 4 will obstruct insertion of the graft 1 unless this is carried within a second sheath (with the consequent increase in size). The only other way to control the hemorrhage is to clamp the introducer sheath 4 on the outside, however, clamping is unlikely to be totally occlusive and may damage the introducer sheath 4. Moreover, the clamp must be removed to allow passage of the graft 1 which produces another period of rapid hemorrhage.

The second advantage of "muzzle loading" over "breech loading" is that if a single sheath 4 is to be used in the "breech loading" technique, the graft 1 must be placed within the introducer 4 at the time of operation. This can be a tricky procedure, especially when the outer end of the introducer sheath 4 is issuing a continual stream of blood.

FIG. 14 shows the common femoral artery 10; proximal (downstream) end 19 of the introducer sheath 4; tubular carrier 21; iliac artery 34; aorta 2; aortic aneurism 20; dilator head 22; and central control means 26. FIG. 15 shows the graft 1 implanted in the aorta 2 at the site of the aortic aneurysm 20.

In the "muzzle loading" technique the graft 1 is inserted into the distal (upstream) end of the introducer sheath 4. The introducer sheath 4 is thin walled, smooth, flexible, sterilizable, non-toxic, and is tubular in form. The tubular carrier 21 fits inside the introducer sheath 4. A close match between the sizes of the sheath 4 and carrier 21 helps to eliminate any buckling of the tubular carrier 21 within the sheath 4 while simultaneously limiting the seepage of blood between the carrier 21 and the sheath 4. The tubular carrier 21 has a dilator 22 attached to the distal (upstream) end which has a conical tip 75 to facilitate the atraumatic passage of the apparatus from the groin into the upper end of the aneurysm. The dilator 22 is also

provided with a cylindrical portion 74 on its proximal (downstream) end which mates with the introducer sheath 4.

The introducer sheath 4 fits over the cylindrical portion 74 of the dilator head 22. A tiny lip 27 at the junction between cylindrical portion 74 and conical portion 75 of the dilator head 22 overlaps the end of the introducer sheath 4 so that no edges are presented to the arterial lumen (or the thrombus that lines the aneurysm) during introduction of the apparatus. This reduces the trauma to vessels and minimizes the chance of dislodging a piece of thrombus that could embolize into the kidneys or lower limbs.

The central control means 26 may take the form of a catheter which extends the entire length of the carrier to the tip of the dilator head 22 so that its lumen can be used for the injection of angiographic dye or as a means of threading the apparatus over a previously placed guide wire. Alternatively, the central control means 26 may pass all the way through the dilator head 22 and slide back and forth within the carrier 4 so that it may function as a guide wire itself. This has been found to be useful in the technique of percutaneous insertion.

In the "breech loading" device, the introducer sheath 4 is a tubular structure having a uniform-diameter and is made of the same material as the "muzzle loading" introducer sheath 4. With this design, the tubular carrier 21 does not have a dilator 22 because the introducer sheath 4 can be carried into position around a standard dilator, which would then be removed before insertion of the tubular carrier 21 with the graft 1.

FIG. 16 shows the tubular carrier 21; mooring loops 39; central control wire 15; and apertures 29, 29', 101, and 101' in the wall of tubular carrier 21.

FIG. 17 shows the tubular carrier 21; mooring loops 39 and 39'; apertures 29, 29', 101 and 101' in the wall of the tubular carrier 21; and central control thread 25.

All "muzzle loading" (and some "breech loading") devices use a central control means 26 that runs up the center of the tubular carrier 21, to which the graft 6 may be moored, and which is used for maintaining the axial position of the graft 1 during removal of the introducer sheath 4. This central control means 26 can take one of several forms, including a flexible shaft 115 (such as a stainless steel wire or a narrow catheter) (as shown in FIG. 16) or a simple thread 25 (as shown in FIG. 17) that passes up the center of the tubular carrier 21, through the mooring loops 39 and 39', and then doubles back through the center of the tubular carrier 21 to its point of origin outside the patient. In the absence of mooring loops 39 and 39', this thread 25 can exit an aperture (29, 29', 101 and 101'), pass through an elbow 7 of the spring assembly 6, traverse the apertures to the opposite elbow 7 of the spring assembly 6 (which it also encircles), pass back into the lumen of the carrier 21 through an aperture (29, 29', 101, and 101') and thereby return to the proximal end of the catheter 21. Release of the mooring loops 39 and 39' is accomplished by withdrawing the central control shaft 115 from the tubular carrier 21 or by releasing one end of the central control thread 25, which is then removed from the tubular carrier 21. If each end of the graft 1 is desired to be controlled and positioned independently of the other, the central control shaft 115 can be partially withdrawn to a point in between the two sets of mooring loops 39 and 39'. If the central control means 26 is a central control thread 25 (instead of a flexible shaft 115), multiple threads 25 can be used, one for each set of mooring loops 39 and 39'.

Because it has no dilator head, the carrier of the "breech loading" device need not traverse the graft 1 to the distal (upstream) end of the introducer sheath 4. Instead, it can end at the graft 1 which would be pushed rather than pulled from the sheath 4. No attachment to the graft 1 would then be needed, but the graft 1 would have to be more rigid and placement would be less precisely controlled.

The "muzzle loading" method will now be described. To assemble the apparatus prior to insertion, the central control means 26 is inserted through the entire length of the tubular carrier 21, which, in turn, is inserted through the entire length of the introducer sheath 4. With the end of the tubular carrier 21 and central control means 26 protruding past the top of the introducer sheath 4, the graft 1 is slid over the dilator head 22 and down the outside of the tubular carrier 21 until positioned directly below the tapered dilator head 22 of the tubular carrier 21. As shown in FIG. 16, the distal (upstream) end of the graft 1 is then moored around the central control means 26 with a mooring loop 39 that engages the spring assembly 6, or is sutured to the graft 1. The mooring loop 39 enters the tubular carrier 21 via the aperture 29 and 29' and forms a mooring loop 39 which engages the central control means 26 so that the mooring loops 39 cannot exit the carrier 21 while the control means 26 occupies the longitudinal opening of the tubular carrier 21. These mooring loops 39 will remain attached to the graft 1 or springs 6 after placement of the graft 1. The mooring loops 39 are preferably made of a monofilament material of low thrombogenicity that in some applications may be biodegradable. When the central control means 26 is withdrawn, mooring loops 39 are free to exit the tubular carrier 21. The proximal (downstream) end of the graft 1 can also be secured in the same manner through a second set of mooring loops 39' passing through a second set of apertures 101 and 101' in the tubular carrier 21, thereby facilitating independent positioning of the two ends of the graft 1. Once the graft 1 is compressed, the introducer sheath 4 is slid over the tubular carrier 21 and the edge of the introducer sheath

4 is fitted snugly against the lip 27 of the dilator head 22. The barbs 10 on the distal (upstream) spring assembly 12 are completely covered by the introducer sheath 4. The apparatus is now ready for insertion.

FIG. 18 is a longitudinal cross-sectional view of an alternative embodiment of the carrier catheter that employs a different form of central control means and shows cantilevered hooks 100, outer carrier 102, lower catheter 104, and dilator head 22. In this embodiment, a pair of concentric catheters is bonded at the distal (upstream) end such that when the inner catheter 104 is pulled in the proximal (downstream) direction from outside the body, the outer catheter 102 bulges out. The graft 1 is held in position on the outer catheter 102 by means of cantilevered hooks 100 attached to the outer surface of the outer catheter 102. These hooks 100 engage the spring assembly 6 of the graft 1 during insertion and prevent the graft 1 from changing its axial position while the introducer sheath 4 is withdrawn. The graft 1 is released from the hooks 100 when the outer catheter 102 is withdrawn.

These methods of securing the graft to the carrier for selective release are required because the outward expansion of the graft against the sheath generates considerable friction that must be overcome in order to extrude the graft. Without such a mechanism, the graft would move with the sheath and would be imprecisely extruded. In order to minimize the forces involved in extrusion, the sheath is constructed of a material (such as Teflon™) which has a low friction surface or is coated with a lubricous material (such as hydragel polymer).

The insertion procedure may be a surgical procedure or may be accomplished percutaneously using a guide wire. In the surgical approach, for example, the femoral artery 30 is exposed through a short groin incision. Heparin is administered intravenously, hemostatic clamps or bands are applied, and the femoral artery 30 is opened. The complete apparatus is inserted into the open femoral artery 30, and is pushed through the femoral 30 and iliac 34 arteries into the aorta 2. The graft 1 is positioned so as to cover the entire length of the aortic aneurysm 20. Positioning is confirmed through fluoroscopy and angiography. Once the positioning has been confirmed, the introducer sheath 4 is pulled back exposing the distal (upstream) barbed spring assembly 12 and part of the length of the graft 1. The springs expand driving the barb tips 13 into the wall of the aorta 2. Once the entire graft 1 is out of the introducer sheath 4 the central control means 26 is withdrawn. As the central control means 26 is withdrawn past the point where the graft 1 is moored to the central control means 26 via the mooring loops 39, the mooring loops 39 will pass over the end of the central control means 26 and be free to pass through the apertures 29 and 29' in the tubular carrier 21. Blood flow in the aorta 2 aids in opening up the multiply crimped middle portion of the graft 1. Placement is performed in two stages. First, the introducer sheath 4 is withdrawn to expose the distal (upstream) 8 half of the graft 1 which expands and attaches to the wall of the aorta 2. The central control means 26 is then withdrawn to a point between the holes 29 and 29' and 101 and 101' in the tubular carrier 21, leaving only the proximal (downstream) 9 end of the graft 1 attached to the carrier 21. The proximal (downstream) 9 end of the graft 1 can then be positioned independently of the distal (upstream) 8 end of the graft 1. The introducer sheath 4 is then withdrawn over the proximal (downstream) spring assembly 31. When the proximal (downstream) 9 end of the graft 1 is exposed it also expands under the action of the spring assembly 31, driving the barbs 10 (when present) into the wall of the aorta 2. The central control means 26 can then be withdrawn past the point where the central control means 26 engages the second set of mooring loops 39', thereby releasing the graft 1 completely. After the proximal (downstream) spring assembly 31 has been released, the tubular carrier 21, central control means 26, and introducer sheath 4 are removed from the patient's body. The femoral artery 30 is then repaired and the wound closed.

Aortic aneurysms frequently encompass the entire distal aorta. In these cases, there is no normal aorta between the aneurysm and the iliac arteries. In order to provide a secure arterial wall for the attachment of the proximal (downstream) end of the graft, the graft may be placed from the infrarenal aorta, above the aneurysm, into the iliac artery on the side of insertion. Such an application also requires conventional femoro-femoral arterial bypass to restore continuity of the circulation to the contralateral limb and the insertion of an occlusive umbrella to prevent retrograde flow through the contralateral common iliac artery into the aneurysm. FIG. 19 is a longitudinal cross-sectional view of an occlusive umbrella 80. The graft 82 is open proximally, but closed distally, forming an inverted picket 86, which is capped by a blunt tip dilator 90. A barbed 92 spring assembly 88 expands the open end of the graft 82. An umbrella catheter 110 having a longitudinal bore is attached to the inside of the dilator 90 and extends through the central axis of the umbrella 80. A pusher catheter 95 is abutted against the umbrella catheter 110 so that the longitudinal openings 111 and 112 are in alignment. A central pusher wire 93 is inserted through the longitudinal opening 112 of the pusher catheter 95 and through the longitudinal opening 111 of the umbrella catheter 110 until the central pusher wire 93 rests against the blunt tip dilator 90.

FIG. 20 shows an aneurysm 20 that extends from the aorta 2 to an iliac artery 34. The graft 1 is inserted so that it forms a conduit from the aorta 2 to the iliac artery 34. A conventional femoro-femoral bypass

graft 94 is used to convey blood from the side receiving the entire aortic blood flow through the proximal end of the graft to the other limb. The occlusive umbrella 80 prevents arterial blood (which enters the iliac artery 34 via the femoro-femoral bypass 94) from "backing up" into the area between the graft 1 and the aneurysm 20.

Prior to insertion, the occlusive umbrella 80 is squeezed into the distal (upstream) end of introducer sheath 4, until the introducer sheath 4 engages the blunt tip dilator 90 and the umbrella catheter 110 meets the pusher catheter 95. The umbrella catheter 110 and the pusher catheter 95 are kept in alignment by the central pusher wire 93 inserted through longitudinal openings 111 and 112. The apparatus is introduced into the femoral artery 30 through a longitudinal arteriotomy and advanced into the common iliac artery 34. The pusher 95 passes through the lumen of a flexible, thin walled, introducer sheath 4. The occlusive umbrella 80 is extruded from the introducer sheath 4 by applying force to the pusher 95 and central pusher wire 93 while pulling on the introducer sheath 4. Once the springs 88 and hoots 92 are out of the confines of the introducer sheath 4 they expand onto the arterial wall securing the umbrella 80. The pusher catheter 95, pusher wire 93, and introducer sheath 4 are then withdrawn from the femoral artery 30 through the arteriotomy. The arteriotomy is then anastomosed to the distal end of the femoro-femoral bypass 94.

When a "breech loading" introducer sheath is used, the sheath must first be inserted (over a dilator) through the femoral artery to the proximal end of the aneurysm. This can be done percutaneously or via an arteriotomy in the isolated femoral artery. The dilator is then removed, the sheath clamped, and the graft inserted. The graft is forced down the introducer sheath by a control catheter, wire or rod, which may traverse the lumen of the graft and attach the distal end of the graft to the control device or may end bluntly at the lower end of the graft. The latter requires that the graft be sufficiently rigid to withstand the compression necessary to overcome the considerable friction between the sheath and the graft.

Hereinafter described is a bifurcated endovascular graft 150 and the method of insertion thereof for repair of abdominal aortic aneurysm. Bifurcated graft insertion system 160 comprises prosthesis 170 (graft/stent combination), prosthesis delivery system 186, distal limb control system 190, distal stent insertion device 140, distal limb straightening device 130, and twist preventing catheter 120. Many features of the introducer system and the prosthesis are to be found in the various embodiments of the tubular graft insertion system. The others are unique to the bifurcated graft.

The prosthesis comprises a graft and one or more stents. Stents occupy the lumen of the graft orifices. Stents expand the graft and fix it in position.

All stents are preferably of the self-expanding (Gianturco) type of which a segment 201 is depicted in FIG. 21. A complete loop of wire is bent back and forth to form a crown or wheel with recurved points 202 between straight limbs 203. The length and number of limbs vary depending on the materials, the size of the vessel to be grafted, and the size constraints of the introducer system. However, the resting (non-deformed) diameter of a stent always exceeds the diameter of the vessels to be grafted. Cranial stents are attached to the graft. Bends, protrusions or other surface irregularities on the stents are used as a point of attachment 204. Protrusions may take the form of catheters or wires, which may be glued, soldered, or brazed to the stent. All cranial stents bear barbs 205. These sharp metal barbs project outward from the surface of the stent. The barb points caudally, cranially, or in both directions. They are soldered, brazed or glued to a stent at any point. The number of barbs is variable. Caudal stents are used with and without barbs.

Depicted in FIG. 22 is bifurcated graft 206 having a cranial orifice 207 and at least two caudal orifices 208 and 209. The graft resembles trousers. The graft includes a main body 250 and caudal limbs 210 and 213 extending therefrom. Main body 250 includes main bore 251 extending longitudinally therein and having cranial orifice 207. Caudal limb 210 includes bore 252 extending longitudinally therein, communicating with main bore 251, and having caudal orifice 209. Caudal limb 213 includes bore 253 extending longitudinally therein, communicating with main bore 251, and having caudal orifice 208.

Grafts are knitted or woven in one piece from a durable yarn such as polyester. There are no seams. An element of elasticity may be incorporated as a property of the fabric or by subsequent treatments such as crimping. The dimensions of the graft vary according to the dimensions of the infra-renal aorta and the common iliac arteries. In each patient a graft will be selected that has diameters that exceed those of the recipient vessels.

In the majority of cases it is important to preserve blood flow through the internal iliac arteries. Therefore, most grafts will be of such a length that caudal orifices 208 and 209 lie in the common iliac arteries. An alternative embodiment uses grafts that extend through the entire common and external iliac arteries to exit the arterial tree via the femoral arteries. The caudal limb of such a graft may be perforated or constructed of very porous material to permit continued perfusion of the internal iliac artery by leakage.

Contralateral graft limb 210 on the side opposite to the side of insertion is marked with radio-opaque lines or imageable markers 211 and 212. These lines are woven into the cloth of the graft or applied after weaving. The lines may be continuous or interrupted.

These lines or markers need be only imageable with any commercially available medical imaging equipment such as x-rays, CT, MRI, or the like. The radio-opaque line is a fine wire or chain of inert metal. Alternatively, the line is incorporated into an inert paint or plastic. The ipsilateral graft limb 213 needs only at least two radio-opaque markers 214 and 215 at caudal orifice 208.

Prosthesis delivery system 180 comprises central carrier 216 and co-axial introducer sheath 217. The introducer sheath has a constant diameter and wall thickness. The internal diameter of the sheath corresponds to the external diameter of the central carrier along two regions. One region is located caudally at carrier shaft 218, and the other region is located cranially at carrier head 219. In between these two regions is much narrower carrier stem region 220.

The introducer sheath is a thin-walled, large-bore catheter made of flexible, inert plastic with a low coefficient of friction. The wall of the sheath incorporates mechanisms to resist kinking (such as an internal wrap of metal wire). The sheath is of constant diameter and wall thickness, except at cranial orifice 223 where external surface 221 of the sheath tapers to meet outer surface 222 of carrier head 219 in a smooth transition as depicted in the preferred and alternative embodiments of FIGs. 24 and 25. Caudal end 224 of the sheath as depicted in FIG. 26 includes a hemostatic seal 225, which engages outer surface 226 of the carrier shaft 218. The seal incorporates a well-known lock 227 to grip the carrier shaft 226 tightly during introduction and prevent premature exposure of prosthesis 228. The length of the sheath depends on the length of the central carrier. The sheath must cover the entire carrier stem and overlap portions of the carrier head and the carrier shaft.

As depicted in FIGs. 26 and 27, central carrier 216 includes inner catheter 229 and a co-axial outer catheter 230. The inner catheter is of constant diameter and wall thickness. Caudal end 231 of the inner catheter has an injection port 232. Outer catheter 230 has a more complicated construction. Internal lumen 233 matches the outer diameter of inner catheter 229, but the outer diameter of the outer catheter varies. Distally, the outer diameter corresponds to the inner diameter of the introducer sheat as depicted in the embodiment of FIG. 24. This segment of the outer catheter is carrier head 219. Another small dilation 234 as depicted in FIG. 25 is immediately distal to the end of introducer sheath 217, to further enhance the smooth transition from carrier head 219 to sheath 217.

The internal diameter of the introducer sheath about the caudal end thereof also matches the external diameter of the caudal segment of carrier shaft 218. The narrower segment of the central carrier between carrier head 219 and carrier shaft 218 is carrier stem 220. During insertion, prosthesis 228 and its associated catheter systems are compressed into the space between introducer sheath 217 and carrier stem 220.

As depicted in FIG. 23, two pairs of holes 235 and 236 traverse the outer catheter of the carrier stem, one pair at each end of prosthesis 228. As depicted in FIG. 27, small loops of suture 237 and 238 wind around inner catheter 229 at this point, entering and exiting the lumen of outer catheter 230 through the holes. These sutures, as well as suture loops 239 and 240, also traverse some part of prosthesis 228, thereby attaching both ends of the prosthesis to the central carrier. Loops 237-240 (and the prosthesis) are released by removal of inner catheter 229. It is important that the two loops of each set do not cross, otherwise the resulting linkage will prevent release from the central carrier despite removal of the inner catheter.

As depicted in FIG. 26, caudal end 241 of inner and outer catheters 229 and 230 has a short flexible extension (with dimensions and structure similar to carrier stem 220). Both inner and outer catheters have injection ports 232 and 242, respectively, at the caudal end of this extension. The injection ports may be locked together with well-known lock 243 to prevent premature removal of the inner catheter.

As depicted in FIG. 23, cranial end 244 of the carrier shaft (or the caudal end of carrier stem 220) includes annular groove 245 for attachment of the catheters and sutures.

The diameter of carrier head 219 and shaft 218 are determined by the diameter of introducer sheath 217, which in turn is dictated by the volume of the prosthesis. The minimum length of the carrier stem is the distance from the proximal end of the aneurysm to the skin of the groin. The maximum length of the carrier shaft is the length of the introducer sheath (which must exceed the length of the carrier stem). Therefore, central carrier 216 is at least twice as long as the iliac artery and aneurysm combined.

The mechanisms of caudal limb control will now be described. All caudal limb control mechanisms extend from caudal ends of limbs 210 and 213 of graft 206 to the level of the skin. Caudal limb control mechanisms take the form of detachable tubular extensions 246 and 247 of the graft as depicted in FIGs 28 and 29, or, alternatively, combinations of catheters and/or sutures as depicted in FIGs. 32-35. Both mechanisms must be amenable to controlled release from the graft by manipulations of the caudal end thereof which extends outside the body.

As depicted in FIG. 28, tubular extensions 246 and 247 are sutured to the respective caudal ends of limbs 213 and 210 of graft 206 by chain stitches 248 and 249, which unravel when cut. These chain stitches are anchored by respective locking stitches 250 and 251. An alternative mechanism depicted in FIG. 29 involves loops of suture 252 and 253 that pass

along the wall of respective tubular extensions 246 and 247 to the conjunction with graft 206.

Alternatively, as depicted in FIG. 30, a single loop of suture material 254 is used as the primary means of applying traction to one point on the end of the caudal limb 210. Attachment to multiple points on the end of caudal lift 210 is depicted in FIG. 31. When the one side of caudal limb control suture 254 is cut, traction on the other side pulls the end of the suture through the graft and out of the body. Enclosing the suture in catheter 255 reduces the chances of inadvertent tangling. Side ports 256 on catheter 255 in FIG. 32 and multiple side ports 257 and 258 on catheter 255 in FIG. 33 allow traction to be applied to more then one point on the graft without necessarily approximating the wall of limb 210. Knot 259 ensures that suture 254 comes out with catheter 255 when the ends are freed by dividing both sides of the loop. Catheter/suture combinations can also serve more than one function, because the tension is only transmitted through shortest suture 260 as depicted in FIG. 34. Traction on catheter 255 does not tighten suture 261 until suture 260 is cut.

However, the two functions of limb control and guided access to the graft lumen can only be performed simultaneously if they are performed by separate catheters. FIG. 35 depicts caudal limb control catheter 255 of contralateral limb 210. Caudal limb control system 262 includes catheter 255 and suture 263.

As depicted in FIG. 36, guided access to the caudal lumen of contralateral limb 210 is provided by a catheter 264 which is moored to the central carrier in the same manner as loops 237 and 238 on the prosthesis. Contralateral lumen access guidance system 265 becomes tense and inflexible when traction is applied to its outer end. When tense, it functions as a guide wire within the lumen of the stent insertion device 140 as depicted in FIG. 39. Contralateral limb access guidance system 265 is released from central carrier 216 when inner catheter 229 is removed. Mooring loop 266 is attached to the end of the catheter or passes through its lumen to the caudal end (where a cannot prevents suture retraction). Sutures that are tied through side holes 267 in the catheter have a tendency to pull out when tension is applied unless the suture also encircles part of the catheter to distribute traction more evenly as depicted in FIG. 37.

As depicted in FIG. 38, access to the lumen of the ipsilateral limb 213 is guided by the same wire that is used for angiography and for insertion of the delivery system. If traction is to be maintained during insertion of a stent on the ipsilateral side, a caudal limb control catheter 254 is also required on ipsilateral distal limb 213.

The orientation of the contralateral limb (and associated catheters) to the carrier must be constant, because any twists are subsequently reproduced in the relative orientation of the two distal limbs. As an additional precaution, the location of contralateral limb 210 is marked on the outside of the delivery system.

Catheters may be made of any plastic that is flexible yet strong enough to hold sutures with extreme thin-walled construction. All sutures should be strong yet fine enough to pass through small catheters. They should also have a low coefficient of friction, to enhance removal at the end of the procedure. Many monofilament and coated multifilament sutures satisfy these criteria. Catheters must be long enough to be accessible at the groin when the contralateral limb has been pulled into position.

Depicted in FIG. 39 is caudal stent insertion device 140 including stent pusher 271 and outer sheath 268. The basic structure and function of the caudal stent insertion device is similar to prosthesis delivery system 180.

Caudal stent insertion device introducer sheath 268 is of constant diameter and wall thickness, except at cranial orifice 269 where the external surface of the sheath tapers to meet the surface of pusher head 270 in a smooth transition. The sheath is made of flexible, inert plastic with a low coefficient of friction. The wall of the sheath may incorporate mechanisms to resist kinking (such as an internal wrap of metal wire). At the cranial end of stent pusher 271 is pusher head 270, which has an external diameter that matches the internal diameter of the introducer sheath. Pusher shaft 272 also matches the diameter of the introducer sheath. Between the two is a narrow pusher stem 273, which passes through the center of caudal stent 275.

Depicted in FIG. 40 is contralateral limb straightening device 130 for orienting the position of contralateral limb 210 of graft 206. Translocation of the contralateral limb of the bifurcated graft can produce twists. Straightening device 130 is advanced over the distal limb control system onto the end of the distal limb and rotated to remove twists. The contralateral limb straightening device is a catheter or small gauge dilator with a fish-mouth split at cranial end 274. The terminal split occupies a plane that also contains the long axis of the device. When traction is applied to suture 254 of the contralateral distal limb control system, the suture is pulled into the catheter approximating the two walls of the graft. The flattened contralateral limb then slides into the slot of the advancing straightening device. Torsion on the device is transmitted to the end of the graft to straighten any twists.

Depicted in FIG. 41 is an alternative limb straightening device 131 designed primarily for use with the system of tubular graft extensions 246 and 247. The alternative device is a dilator with a soft rounded tip and a bulbous dilation 132 at cranial end 133. The dilatation is pushed into a narrowing of the tubular ex-

tension, which is maintained under tension by traction on the caudal end. The tight fit enables torsional forces to be transmitted to the graft through friction at the surface of the dilatation. In the absence of the tubular graft extensions, the alternative limb straightening device is advanced over contralateral lumen access guidance system 265. The dilatation then engages the inner aspect of the distal limb orifice 209. Alternatively, the dilatation may take the form of a balloon, which is inflated inside caudal limb 210. Whatever form the straightener takes, it must be long enough to reach the end of the caudal limb from the femoral arteriotomy. The diameter is variable, depending on the mechanism of graft attachment. The device must be flexible, yet resist deformation when torsional stresses are applied to the caudal end.

Depicted in FIG. 42 is a sectioned view twist-preventing, double lumen catheter 120. This soft, flexible catheter has two lumens 121 and 122. One is occupied by the cross femoral catheter, while the other is occupied by the angiographic catheter (or wire). Cranial end 123 is slightly tapered for ease of insertion. The catheter resists torsion so that the relative orientation of the two lumens is maintained. The twist-preventing, double lumen catheter is inserted to the point where the two catheters diverge, one passing through the aneurysm to the proximal aorta, the other crossing to the opposite iliac artery.

The method for inserting the prosthesis and use of the insertion instruments is hereinafter described. Patients are selected for this procedure on the basis of radiographic imaging (including angiography) and general physical condition.

The patient is placed in the supine position on a radiolucent operating table. Access to the arterial tree may be obtained by surgical isolation of the femoral vessels in the groin. Alternatively, the insertion may be performed through large introducer sheaths placed. by percutaneous techniques. In the open technique, silastic bands around the common femoral arteries provide proximal hemostasis, while non-crushing clamps provide distal hemostasis. Most patients will be anticoagulated with heparin prior to the interruption of the circulation to the legs.

Insertion is guided by fluoroscopy. When available, digital subtraction processing enhances fluoroscopic images and is used to record angiograms. Another useful feature of digital subtraction imaging equipment is the "roadmapping" function, which combine real time fluoroscopic images with static angiograms. The composite image facilitates guidance of the apparatus through the vascular tree.

An initial angiogram is performed to provide the reference points that guide insertion. Angiography will frequently have been performed as part of the selection procedure, in which case measurements determining graft size and form will already have been taken. After initial angiography the catheter is removed, leaving the guide wire in place.

A wire, suture, catheter or tape is passed from one femoral artery to the other. In one method, a Dormier basket is passed up the ipsilateral femoral artery and opened over the contralateral iliac artery orifice. A catheter or guide wire is threaded up the opposite femoral artery through the wires of the Dormier basket, which is then closed and withdrawn. The procedure is swift and relatively atraumatic, especially if a very soft, flexible catheter is used. An alternative method involves fluoroscopically guided manipulation of the curved tip of a catheter/guide wire system from one iliac artery into the other.

Care must be taken to avoid winding the angiographic catheter around the cross femoral system. This may be accomplished by inserting the angiographic catheter (or wire) through one lumen of a double lumen, twist-preventing catheter 120, while the other lumen is occupied by the cross femoral system (or vice versa).

The introducer system is threaded over the same guide wire that occupied the lumen of the angiographic catheter. Fluoroscopic visualization is relatively easy because all components of the apparatus (except the fabric of the graft) are radio-opaque. The position of the prosthesis is controlled during extrusion by manipulation of the central carrier. When the introducer sheath is withdrawn, the stents expand, opening the graft and fixing it in position. Further withdrawal of the introducer sheath 217 exposes the caudal limb control mechanisms and their attachment to central carrier 216. The caudal limb control mechanisms, such as suture loops 237 and 238 or other catheters, sutures, or tubular graft extensions, are attached to the cross femoral system (catheter, suture, tape or guide wire) using sutures, tape or clips. Traction on the cross femoral system (at the contralateral groin) pulls the contralateral limb 210 into the contralateral iliac artery.

The contralateral limb 210 is sometimes twisted after translocation to the contralateral iliac artery. Twisting is revealed by the fluoroscopic appearance of the radio-opaque lines 211 and 212. The contralateral limb control mechanism such as suture loops 237 and 238 is used to apply traction to other contralateral limb 210 and pull it onto the advancing contralateral limb straightening device 130 or 131. Straightening is guided by the fluoroscopic appearance and the character of the femoral arterial pulse and blood flow.

Stents are occasionally required to prevent retrograde leakage of blood around the caudal limbs 210 and 211 back into the aneurysm. The distal stent insertion device may be passed through the lumen of a tubular graft extension 247. Alternatively, the stent insertion device is passed over a guide wire or over contralateral lumen access guidance system 265. Whichever method is used, it is usually necessary to maintain traction on the caudal limbs using the caudal

limb control mechanism. Insertion of the ipsilateral stent cannot be performed until the delivery system has been removed.

The prosthesis 228 is released from the central carrier 216 by removal of the inner catheter 229. It is important to replace the inner catheter and advance the guide wire through the central lumen before removing the delivery system, because the wire is needed to guide the stent insertion device into the lumen of the ipsilateral caudal limb 213. After stent insertion the wire is needed again to guide insertion of a catheter for completion angiography. If angiographic appearances are satisfactory, the catheters are removed, the arteries repaired, and the wounds closed.

Depicted in FIG. 43 is transluminal arrangement 350 for positioning prosthesis assembly 228 at a particular position in a bifurcated lumen. As depicted in FIGs. 48 and 49, bifurcated lumen 284 is located in aorta 2 with common iliac arteries 34 and 35 extending distally therefrom. Aortic aneurysm 20 is located just proximal the common iliac arteries 34 and 35. Aortic lumen 285 forms the main lumen, whereas common iliac lumens 286 and 287 communicating with the main lumen form the branch lumens.

Prosthesis assembly 228 depicted in FIG. 43 includes bifurcated endovascular graft 206, main spring assembly 301, and limb spring assemblies 302 and 303 (not shown) positioned in respective stent boots 300 and 305. Main spring assembly 301, as well as prosthesis assembly 228, is contained in main container sheath 217 which is, for example, a polytetrafluoroethylene tube. Bifurcated endovascular graft 206 includes main body 250 with ipsilateral limb 213 and contralateral limb 210 extending therefrom and partially over the tops of respective stent boots 304 and 305.

As previously described with respect to FIG. 22, main body 250 includes main bore 251 extending longitudinally therein with cranial orifice 207. Contralateral limb bore 252 and ipsilateral limb bore 253 communicate with main bore 251 and extend longitudinally through respective contralateral limb 210 and ipsilateral limb 213. Contralateral limb 210 has caudal orifice 209, whereas ipsilateral limb 213 has caudal orifice 208. Main spring assembly 301 is positioned through cranial orifice 207 and into bore 251 of the main body for radially expanding the main body of the graft to substantially conform the main body of the graft on the interior wall of main lumen 285. Main spring assembly 301 expands from its compressed state, as shown in FIG. 43, when the prosthesis assembly is positioned in the bifurcated lumen and released from container sheath 217.

Transluminal arrangement 350 includes outer sheath 217 for containing main spring assembly 301 in a compressed state, stent boot sheath 304 for containing ipsilateral spring assemly in a compressed state; stent boot sheath 305 for containing contralateral spring assembly is a compressed state; and main retainer assembly 351 positioned in the main and ipsilateral bores of the graft for retaining prosthesis assembly 228 in the bifurcated lumen while the outer sheath is withdrawn from the prosthesis asssembly releasing the main spring assembly from its compressed state.

Similar to previously described central carrier 216, main retainer assembly comprises elongated member 352 having dilator head 353 at the distal end thereof. The dilator head serves to facilitate penetration of the transluminal arrangement within the bifurcated lumen and minimizes deleterious blood flow during positioning of the transluminal arrangement. Elongated member 352 also includes an intermediate carrier stem region including outer catheter 318, hollow connector sleeve 354 with lateral apertures 355 and 356 formed therein, and inner catheter 319 extending longitudinally through the elongated member including the outer catheter and connector sleeve. Connector sleeve 354 interconnects segments of outer catheter 318 and facilitates as to permit attachment of sutures 357 and 358 to inner catheter 319 through respective apertures 355 and 356. One end of attachment sutures 357 and 358 are tied around the outer surface of outer catheter 318, whereas other end of the sutures are tied around the outer surface of inner catheter 319 through the connector sleeve apertures. Attachment sutures 357 and 358 are looped through the opposite sides of main spring assembly 301 for retaining the prosthesis assembly in the bifurcated lumen while outer sheath 217 is withdraw from the prosthesis assembly releasing the main spring assembly from its compressed state. The outer sheath includes longitudinal bore 359 in which the prosthesis assembly is positioned during insertion of the assembly into the bifurcated lumen. Attachment sutures 357 and 358 for a contraction assembly for temporarily pulling main spring assembly 301 to a compressed state when prosthesis assembly 228 is positioned within main outer sheath 217. The distal end of the outer sheath is positioned next to the proximal end of dilator head 353 to facilitate easy insertion of the transluminal arrangement into the bifurcated lumen.

Elongated member 352 also includes a carrier shaft region 360 similar to carrier shaft region 218 of which annular recess 309 is formed therein.

FIG. 44 depicts a partially sectioned side view of ipsilateral limb spring assembly 102 in a compressed state. The spring assembly is attached to the inside of ipsilateral limb 213 via sutures 315 and 316 and is contained in stent boot sheath 304. When the prosthesis assembly is properly positioned about aneurysm 20, ipsilateral spring assembly 302 is released from its compressed state to radially expand limb 213 and substantially conform the limb to the interior wall of common iliac artery 34. Stent boot sheath 304

forms a container for containing ipsilateral spring assembly 302 in a compressed state. Suture 314 is temporarily attached to ipsilateral spring assembly 302 for retaining the spring assembly in the stent boot sheath during positioning of the prosthesis assembly in the bifurcated lumen. Suture 314 forms a release mechanism for releasing the ipsilateral spring assembly when the prosthesis assembly is positioned in the bifurcated lumen and, in particular, when ipsilateral limb 213 is properly positioned in common iliac artery 34. After suture 314 is detached from the ipsilateral spring assembly, stent boot 304 is withdrawn from the spring assembly, releasing it from its compressed state. When released from its compressed state, ipsilateral spring assembly 302 radially expands graft limb 213 to substantially conform the limb on an interior wall of iliac artery lumen 286.

Stent boot 304 is a tubular container such as a sheath or short piece of polytetrafluoroethylene tube for containing ipsilateral spring assembly 302 therein in a compressed state. Ipsilateral spring assembly 302 is attached along its midsection to contralateral graft limb 213 inside limb bore 253 with sutures 315 and 316. Attachment sutures 315 and 316 are placed cranially from caudal orifice 208 to allow the caudal end of the graft limb to extend over the top of stent boot 304. Attachment sutures 314 and 317 are temporarily attached to ipsilateral spring assembly 302 for retaining the spring assembly in stent boot 304. One end of attachment sutures 314 and 317 are tied around outer catheter 318 of the transluminal positioning arrangement, whereas the other end of the sutures are tied around inner catheter 319 through apertures 320 and 321 of connector sleeve 322. The inner catheter of the positioning arrangement forms part of a release mechanism that is temporarily attached to the ipsilateral spring assembly for releasing attachment sutures 314 and 317. Attachment sutures 314 and 317 and inner catheter 319 form a retainer mechanism for retaining ipsilateral spring assembly 302 in stent boot 304. Connector sleeve 322 is a short length of tubing having apertures 320 and 319 formed laterally therethrough. The connector sleeve has an inner diameter approximating the outer diameter of outer catheter 318. Outer catheter 318 is cut and inserted into the opposite ends of the connector sleeve and bonded thereto using, for example, medical grade adhesive. Inner catheter 319 passes through the passageway of the connector sleeve and outer catheter for retaining attachment sutures through the lateral apertures in the sleeve.

FIG. 45 depicts a partially sectioned side view of contralateral spring assembly 304, attached to the inside of contralateral lift 210, and contained in stent boot 305. Limb control catheter 255 is attached proximally to stent boot 305 and has suture 254 extending longitudinally through catheter lumen 306. Suture 254 is temporarily attached to contralateral spring assembly for retaining the spring assembly in the stent boot during positioning of the prosthesis assembly in the bifurcated lumen. Suture 254 forms a release mechanism for releasing the contralateral spring assembly when the prosthesis assembly is positioned in the bifurcated lumen and, in particular, when contralateral limb 210 is positioned in common iliac artery 35. After suture 254 is detached from the contralateral spring assembly, stent boot 305 is withdrawn from the spring assembly, releasing it from its compressed state. When released from its compressed state, contralateral spring assembly 303 radially expands limb 210 to substantially conform the limb on an interior wall of iliac artery lumen 287. Limb control catheter 255 is a commercially available copolymer tube to which stent boot 305 is integrally formed or attached thereto, for example, using medical grade adhesive. Stent boot 305 is a tubular container such as a short piece of polytetrafluoroethylene tube for containing contralateral spring assembly 303 therein in a compressed state. Contralateral spring assembly 303 is attached along its midsection to contralateral graft limb 210 inside limb bore 255 with sutures 307 and 308. Attachment sutures 307 and 308 are placed cranially from caudal orifice 209 to allow the caudal end of the graft limb to extend over the top of stent boot 305. Contralateral spring assembly 303 can include one or bore barbs for digging into the vessel wall and more securely anchoring the prosthesis assemly. However, the contralateral spring assembly can be used with or without these barbs. Retainer suture 254 is temporarily attached to carrier shaft annular recess 309 via suture 310.

FIG. 46 depicts a partially sectioned side view of stent boot 305 attached to control limb delivery catheter 255 which is positioned in longitudinal lumen 311 of contralateral limb straightening device 130. A plurality of longitudinal splines 312 is formed in the proximal end of stent boot 305 to match a corresponding plurality of splines 313 positioned around the distal end of straightening device lumen 311. The mating splines engage each other to rotate the stent boot and contralateral limb for proper positioning within the common iliac artery. Markers are positioned in the graft limb for radiographic imaging.

FIG. 47 depicts prosthesis assembly 228 positioned in bifurcated lumen 284 of aorta 2 and common iliac arteries 34 and 35. Main spring assembly 301 has been released from its compressed state and radially expanded main body 250 of the graft to substantially conform the main body of the graft on the interior wall of main lumen 285 of the aorta. Similarly, ipsilateral spring assembly 302 has been released from its compressed state and elongated member 352 and radially expanded ipsilateral limb 213 of the graft to substantially conform the ipsilateral limb on an interior wall of lumen 286 of common iliac artery 34. Contralateral spring assembly 303 has been released

from its compressed state and radially expanded contralateral limb 210 to substantially conform the contralateral limb of the graft on an interior wall of lumen 287 of common iliac artery 35. Control limb delivery catheter 255 and stent boot 305 have been withdrawn from the contralateral spring assembly allowing it to expand the contralateral limb of the graft.

The method of positioning the prosthesis assembly at the particular position in bifurcated lumen 284 includes providing first and second access sites 283 and 361 to branch lumens 286 and 287 in respective common iliac arteries 34 and 35 in a well-known manner. As previously described with respect to FIGs. 48 and 49, the guide is provided between access sites 283 and 361 via the branch lumens. Transluminal arrangement 350 including retainer assembly 351, elongated member 352, and prosthesis assembly 228 attached thereto are positioned within the bifurcated lumen. Outer sleeve 217 is withdrawn from the prosthesis assembly, and control limb delivery catheter 255 guides the contralateral limb of the graft into branch lumen 287 of iliac artery 35. The attachment sutures are released from the main, ipsilateral and contralateral spring assemlies positioning the prosthesis in the bifurcated lumen. Stent boots 304 and 305 are removed from their respective spring assemblies during withdrawal of retainer assembly 352 and control limb delivery catheter 255.

The transluminal arrangement for positioning a prosthesis assembly at a particular position in a bifurcated lumen and the method of placement has been illustrated and described in the drawing and the foregoing description, the same is to be considered illustrative and not restrictive in character. It is to be understood that only the preferred embodiment has been shown and that all changes and modifications that come within the scope of the claims are to be protected. In particular, stent boots 304 and 305 have been referred to as containers or sheaths and are typically formed from a thin polytetrafluoroethylene tube of material. The stent boots are either affixed to the outer catheter of the retainer assembly or slidable thereon. Similarly, stent boot 304 is attached using, for example, medical grade adhesive, are slidable at the end of the control delivery catheter. Outer sheath 217 is also a container or sheath of, for example, a semi-rigid polytetrafluoroethylene material for containing the prosthesis assembly therein. The spring assemblies are of the Gianturco Z-stent type as previously described with or without barbs for more securely affixing the prosthesis assembly to the wall of the bifurcated lumen. Any type of radially expanding spring assembly or stent is contemplated whether the spring assembly or stent is automatically expanded when released from a container or expanded with a dilator balloon and the like.

Claims

1. An arrangement for translumenally positioning a prosthesis assembly (1,12,31) of predetermined shape and size at a particular position on an internal wall (20) of a lumen, said assembly comprising a graft (1) associated with a spring arrangement (12,31), said arrangement comprising an outer sheath (4) for surrounding the said assembly when the latter is located at the said particular position, and means (36,21,26) for retaining the said assembly at the said particular position whilst the outer sheath is being removed, characterised in that the retaining means has connected thereto an attachment arrangement (36) to be temporarily attached to the said assembly at one or more positions remote from the proximal end of the said assembly.

2. An arrangement according to claim 1, characterised in that the retaining means comprises an elongated member (21) to be extended within the said assembly, and in that the attachment arrangement is extended between the said elongated member and the said assembly at the said one or more positions.

3. An arrangement according to claim 2, characterised in that the elongated member is tubular and has a dilator head (22) at the distal end thereof, said head serving to facilitate penetration of the arrangement within the lumen, and to minimize deleterious blood flow through the lumen during the positioning of the assembly.

4. An arrangement according to claim 3, characterised in that a contraction arrangement (36,21) is provided to temporarily pull the said assembly inwardly to a compressed condition whilst the assembly is within the sheath, and in that a disabling arrangement (26) is provided for expandably releasing the said assembly either during or after removal of the sheath.

5. An arrangement according to claim 4, characterised in that the contraction and disabling arrangements form part of the said attachment arrangement, and in that part of the contraction and disabling arrangements are located and controlled from within the elongated tubular member.

6. An arrangement according to claim 5, characterised in that the attachment arrangement comprises one or more connectors each in the form of sutures (36) connected at one end to the said assembly and at the other end to inside of the elongated tube via apertures (29,101) and in that the disabling arrangement (26) is provided for releas-

from its compressed state and radially expanded contralateral limb 210 to substantially conform the contralateral limb of the graft on an interior wall of lumen 287 of common iliac artery 35. Control limb delivery catheter 255 and stent boot 305 have been withdrawn from the contralateral spring assembly allowing it to expand the contralateral limb of the graft.

The method of positioning the prosthesis assembly at the particular position in bifurcated lumen 284 includes providing first and second access sites 283 and 361 to branch lumens 286 and 287 in respective common iliac arteries 34 and 35 in a well-known manner. As previously described with respect to FIGs. 48 and 49, the guide is provided between access sites 283 and 361 via the branch lumens. Transluminal arrangement 350 including retainer assembly 351, elongated member 352, and prosthesis assembly 228 attached thereto are positioned within the bifurcated lumen. Outer sleeve 217 is withdrawn from the prosthesis assembly, and control limb delivery catheter 255 guides the contralateral limb of the graft into branch lumen 287 of iliac artery 35. The attachment sutures are released from the main, ipsilateral and contralateral spring assemlies positioning the prosthesis in the bifurcated lumen. Stent boots 304 and 305 are removed from their respective spring assemblies during withdrawal of retainer assembly 352 and control limb delivery catheter 255.

The transluminal arrangement for positioning a prosthesis assembly at a particular position in a bifurcated lumen and the method of placement has been illustrated and described in the drawing and the foregoing description, the same is to be considered illustrative and not restrictive in character. It is to be understood that only the preferred embodiment has been shown and that all changes and modifications that come within the scope of the claims are to be protected. In particular, stent boots 304 and 305 have been referred to as containers or sheaths and are typically formed from a thin polytetrafluoroethylene tube of material. The stent boots are either affixed to the outer catheter of the retainer assembly or slidable thereon. Similarly, stent boot 304 is attached using, for example, medical grade adhesive, are slidable at the end of the control delivery catheter. Outer sheath 217 is also a container or sheath of, for example, a semi-rigid polytetrafluoroethylene material for containing the prosthesis assembly therein. The spring assemblies are of the Gianturco Z-stent type as previously described with or without barbs for more securely affixing the prosthesis assembly to the wall of the bifurcated lumen. Any type of radially expanding spring assembly or stent is contemplated whether the spring assembly or stent is automatically expanded when released from a container or expanded with a dilator balloon and the like.

Claims

1. An arrangement for translumenally positioning a prosthesis assembly (1,12,31) of predetermined shape and size at a particular position on an internal wall (20) of a lumen, said assembly comprising a graft (1) associated with a spring arrangement (12,31), said arrangement comprising an outer sheath (4) for surrounding the said assembly when the latter is located at the said particular position, and means (36,21,26) for retaining the said assembly at the said particular position whilst the outer sheath is being removed, characterised in that the retaining means has connected thereto an attachment arrangement (36) to be temporarily attached to the said assembly at one or more positions remote from the proximal end of the said assembly.

2. An arrangement according to claim 1, characterised in that the retaining means comprises an elongated member (21) to be extended within the said assembly, and in that the attachment arrangement is extended between the said elongated member and the said assembly at the said one or more positions.

3. An arrangement according to claim 2, characterised in that the elongated member is tubular and has a dilator head (22) at the distal end thereof, said head serving to facilitate penetration of the arrangement within the lumen, and to minimize deleterious blood flow through the lumen during the positioning of the assembly.

4. An arrangement according to claim 3, characterised in that a contraction arrangement (36,21) is provided to temporarily pull the said assembly inwardly to a compressed condition whilst the assembly is within the sheath, and in that a disabling arrangement (26) is provided for expandably releasing the said assembly either during or after removal of the sheath.

5. An arrangement according to claim 4, characterised in that the contraction and disabling arrangements form part of the said attachment arrangement, and in that part of the contraction and disabling arrangements are located and controlled from within the elongated tubular member.

6. An arrangement according to claim 5, characterised in that the attachment arrangement comprises one or more connectors each in the form of sutures (36) connected at one end to the said assembly and at the other end to inside of the elongated tube via apertures (29,101) and in that the disabling arrangement (26) is provided for releas-

ing the sutures from inside the elongated tube.

7. An arrangement according to any one preceding claim, in which the lumen for receiving the graft is bifurcated, characterised in that the graft has a common section (250) and two bifurcated sections (213,210) shaped and sized to conform to the respective parts of the bifurcated lumen, in that the said spring arrangement is associated with the common section of the graft and one bifurcated section (213), and in that another spring arrangement is designed to be translumenally positioned within the said other bifurcated section (210).

8. An arrangement according to claim 7, characterised in that one or more identification markers (211,212) are provided on at least the said other bifurcated graft section.

9. An arrangement according to claim 7 or 8, characterised in that the said other bifurcated graft section is provided with an arrangement whereby the said other section can be translumenally drawn into position within the respective lumen part.

10. An arrangement according to any one preceding claim, characterised in that the or each spring or graft assembly comprises at least barbs (13) at the distal end of the assembly.

11. An arrangement according to any one of claims 1 to 6, characterised in that one end of the graft is sealed (80) to prevent flow of blood through the lumen.

12. A prosthesis for translumenally repairing an aneurysm, characterised by a bifurcated endovascular graft (206) having a main body (250) and first and second limbs (213,210) extending therefrom, said main body including a main bore extending longitudinally therein and having a cranial orifice (207), said first limb including a first bore (253) extending longitudinally therein, communicating with said main bore, and having a first caudal orifice (208), said second limb (210) including a second bore (252) extending longitudinally therein, communicating with said main bore, and having a second caudal orifice (209); and imageable marker means (211,212) extending along at least said first limb.

13. A transluminal arrangment for positioning a prosthesis assembly at a particular position in a bifurcated lumen, the bifurcated lumen including a main lumen and a first and a second branch lumen communicating with and extending from the main lumen, said prosthesis assembly including a bifurcated endovascular graft having a main body and a first and a second limb extending therefrom, said main body including a main bore extending longitudinally therein and having a cranial orifice, said first limb including a first bore extending longitudinally therein, communicating with said main bore, and having a first caudal orifice, said second limb including a second bore extending longitudinally therein, communicating with said main bore and having a second caudal orifice, said assembly including a main spring assembly and a first spring assembly each having a compressed state, said main spring assembly radially expanding said main body of said graft to substantially conform said main body of said graft on an interior wall of the main lumen when said prosthesis assembly is positioned at a particular position in the bifurcated lumen and said main spring assembly is released from said compressed state, said first spring assembly radially expanding said first limb of said graft to substantially conform said first limb of said graft on an interior wall of the first branch lumen when said prosthesis assembly is positioned at the particular position in the bifurcated lumen and said first spring assembly is released from said compressed state, said transluminal arrangement comprising:

main container means for containing said main spring assembly in said compressed state;

first container means for containing said first spring assembly in said compressed state;

retainer means positioned in said main and first bores of said graft for retaining said prosthesis assembly at the particular position in the bifurcated lumen while main container means is withdrawn from said prosthesis assembly releasing said main spring assembly from said compressed state.

14. A transluminal arrangement for positioning a prosthesis assembly at a particular position in a bifurcated lumen, the bifurcated lumen including a main lumen and first and a second branch lumen communicating with and extending from the main lumen, said prosthesis assembly including a bifurcated endovascular graft having a main body and a first and a second limb extending therefrom, said main body including a main bore extending longitudinally therein and having a cranial orifice, said first limb including a first bore extending longitudinally therein, communicating with said main bore, and having a first caudal orifice, said second limb including a second bore extending longitudinally therein, communicating with said main bore and having a second caudal orifice, said assembly including a main spring as-

sembly, a first spring assembly, and a second a spring assembly each having a compressed state, said main spring assembly radially expanding said main body of said graft to substantially conform said main body of said graft on a interior wall of the main lumen when said prosthesis assembly is positioned at a particular position in the bifurcated lumen and said main spring assembly is released from said compressed state, said first spring assembly radially expanding said first limb of said graft to substantially conform said first limb of said graft on an interior wall of the first branch lumen when said prosthesis assembly is positioned at the particular position in the bifurcated lumen and said first spring assembly is released from said compressed state, said second spring assembly radially expanding said second limb of said graft to substantially conform said second limb of said graft on an interior wall of the second branch lumen when said prosthesis assembly is positioned at a particular position in the bifurcated lumen and said second spring assembly is released from said compressed state, said transluminal arrangement comprising:

main container means for containing said main spring assembly ins aid compressed state;

first container means for containing said first spring assembly in said compressed state;

second container means for containing said second spring assembly in said compressed state;

main retainer means positioned in said main and first bores of said graft for retaining said prosthesis assembly at the particular position in the bifurcated lumen while said main container means is withdrawn from said prosthesis assembly releasing said main spring assembly from said compressed state;

first retainer means temporarily attached to said first spring assembly for retainer said first spring assembly in said first container means; and

second retainer means temporarily attached to said second spring assembly for retaining said second spring assembly in said second container means.

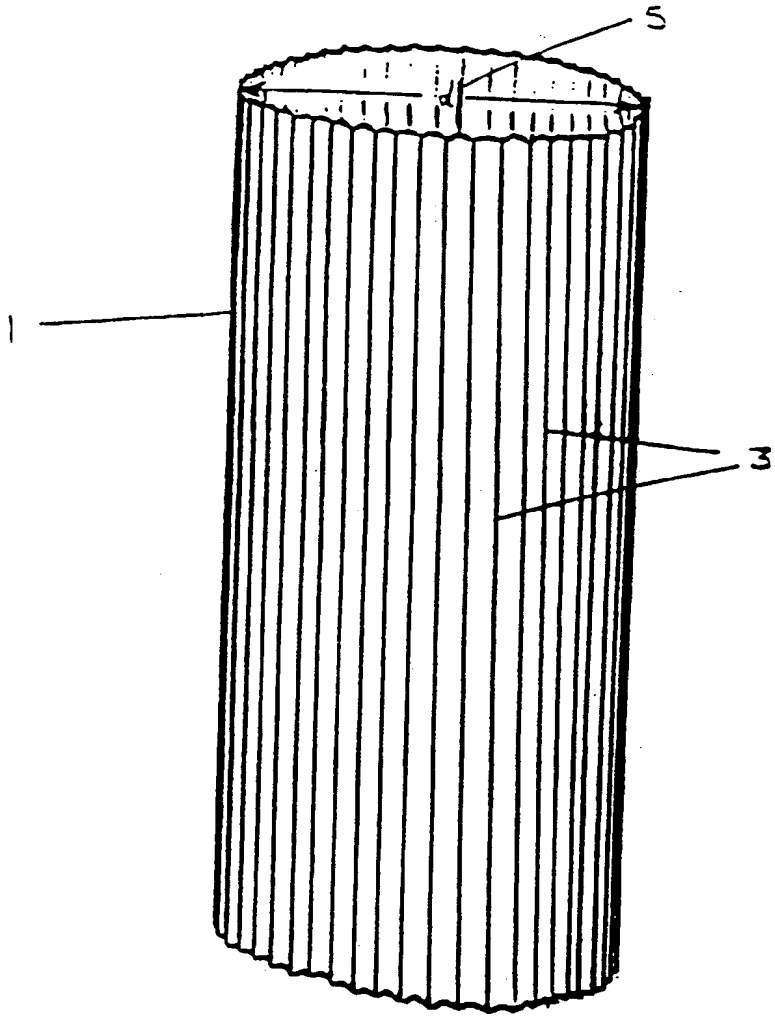

FIG. 1

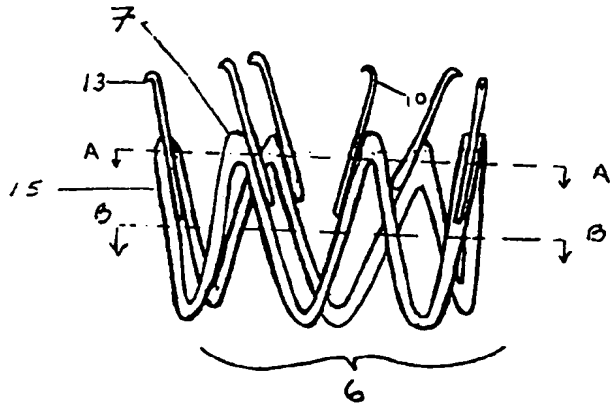

FIG. 2

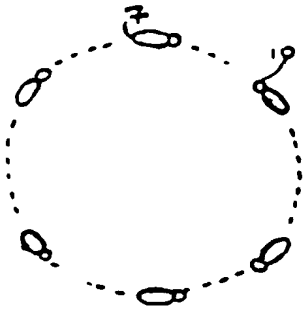

FIG. 3

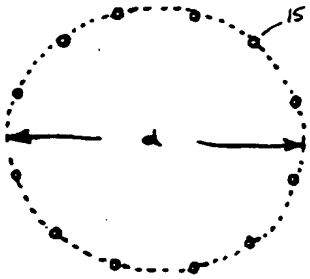

FIG. 4

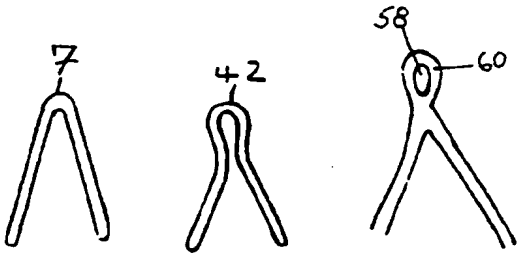

FIG. 5

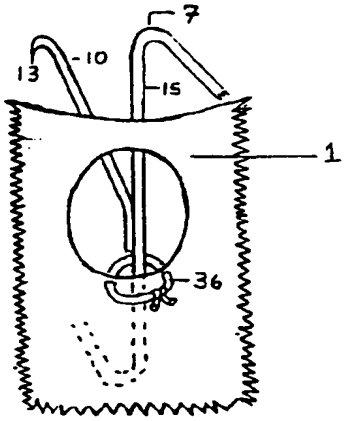

FIG. 6

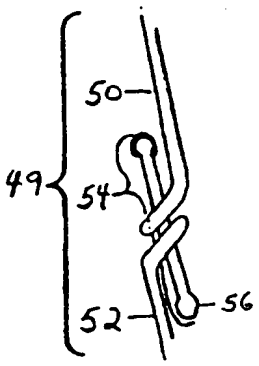

FIG. 7

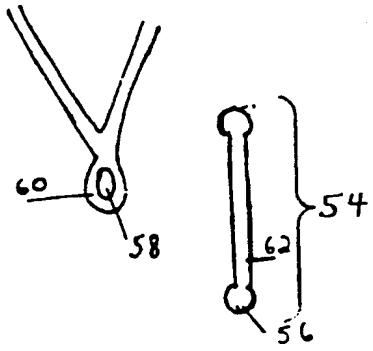

FIG. 8

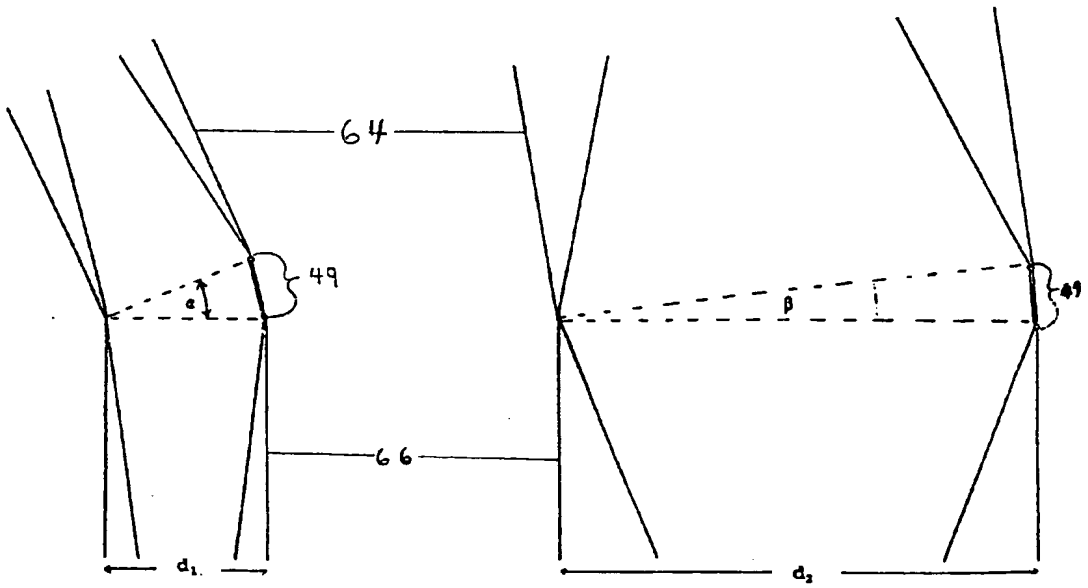

FIG. 9-A

FIG. 9-B

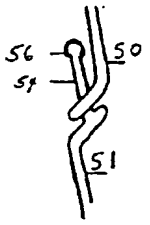

FIG. 10

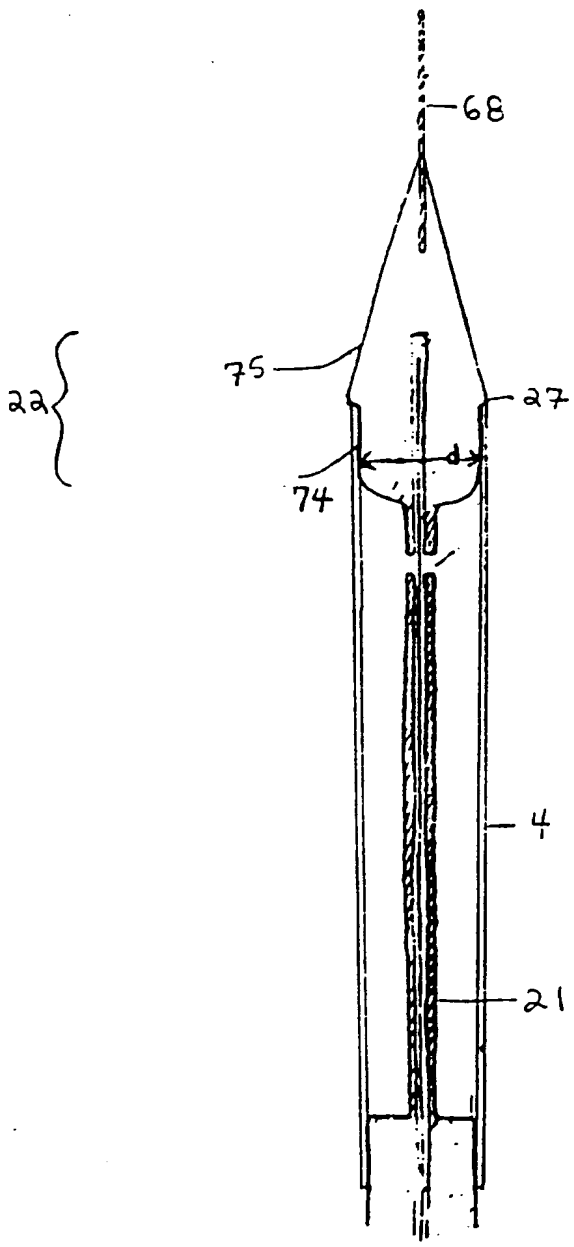

FIG. 11

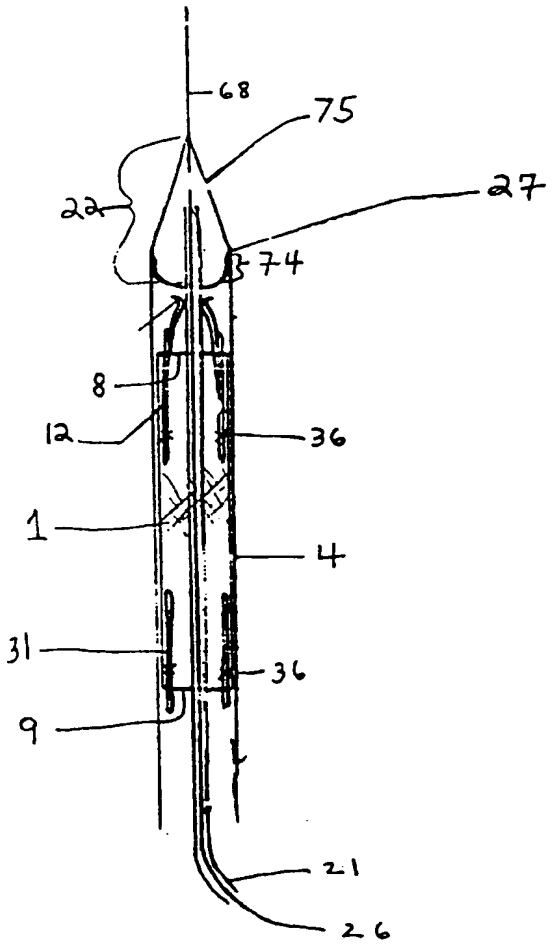

FIG. 12

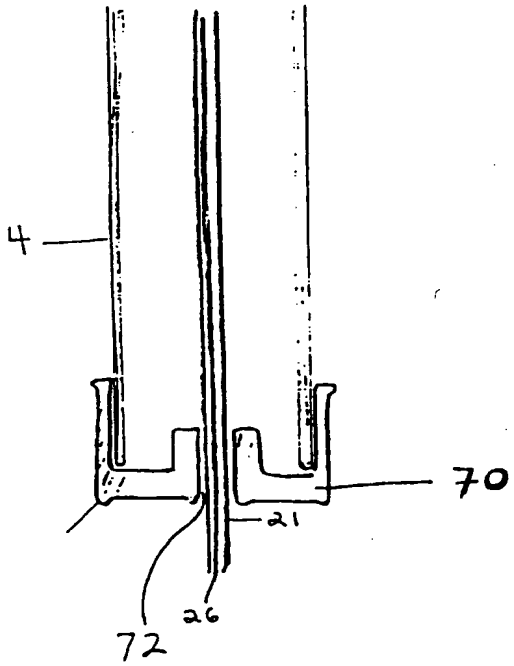

FIG. 13

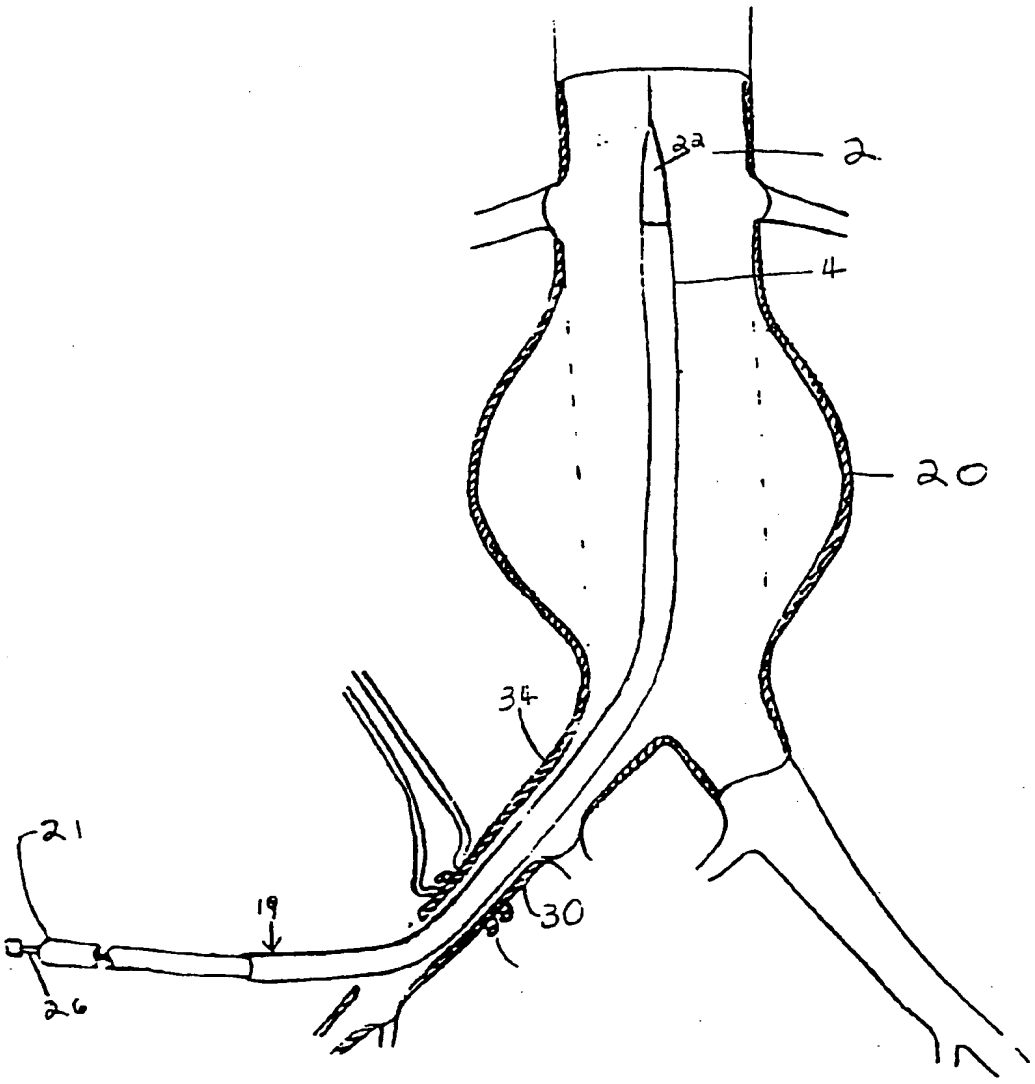

FIG. 14

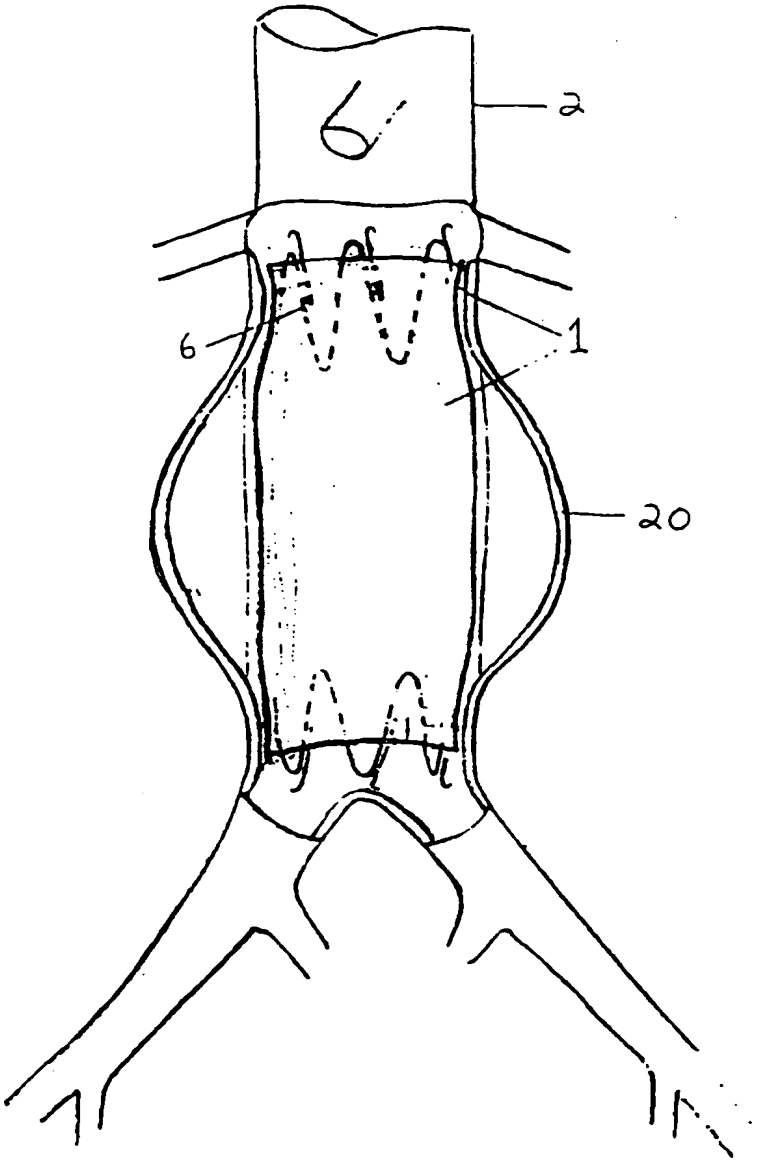

FIG. 15

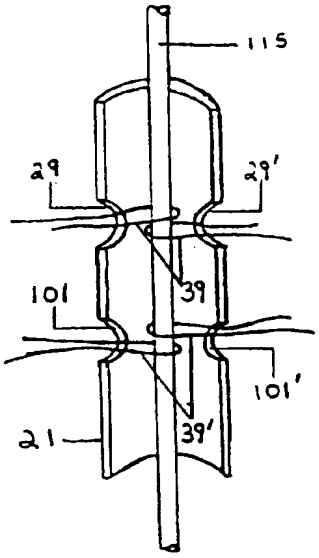

FIG. 16

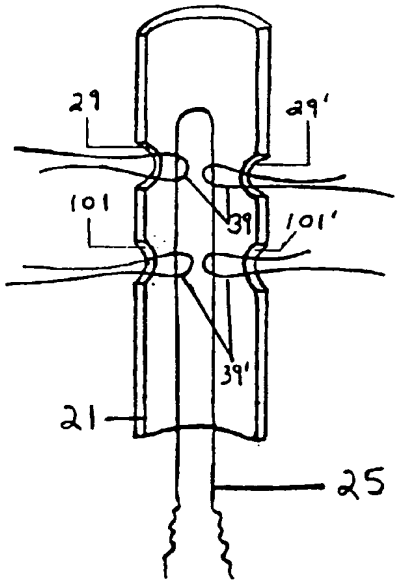

FIG. 17

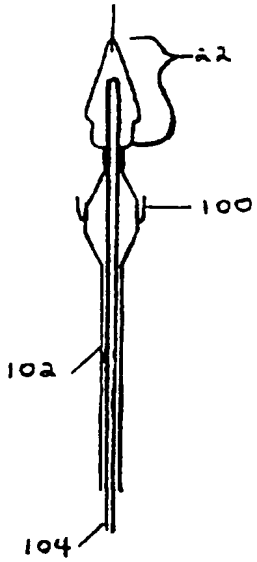

FIG. 18

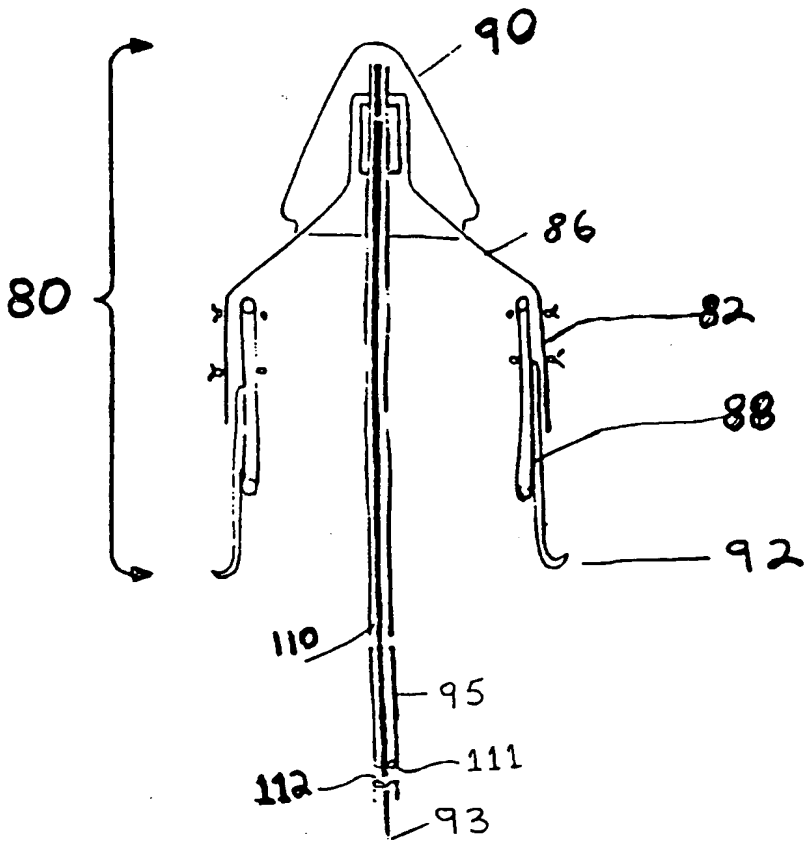

FIG. 19

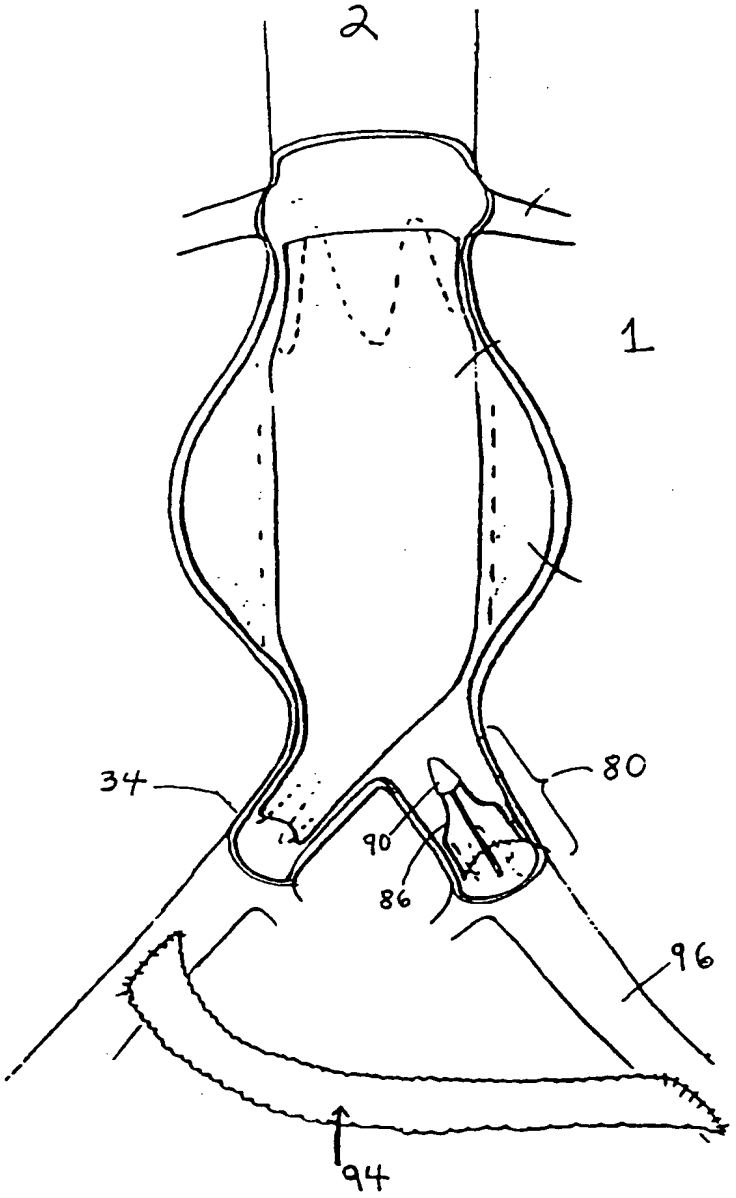

FIG. 20

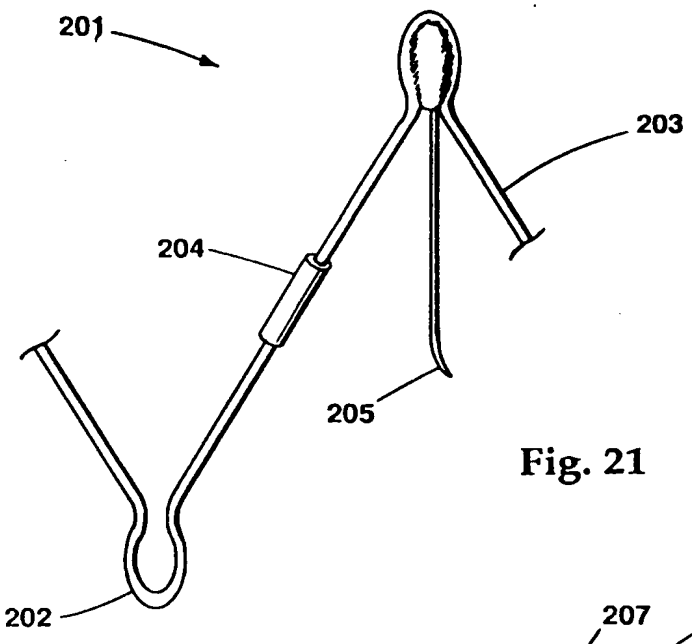
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Fig. 21

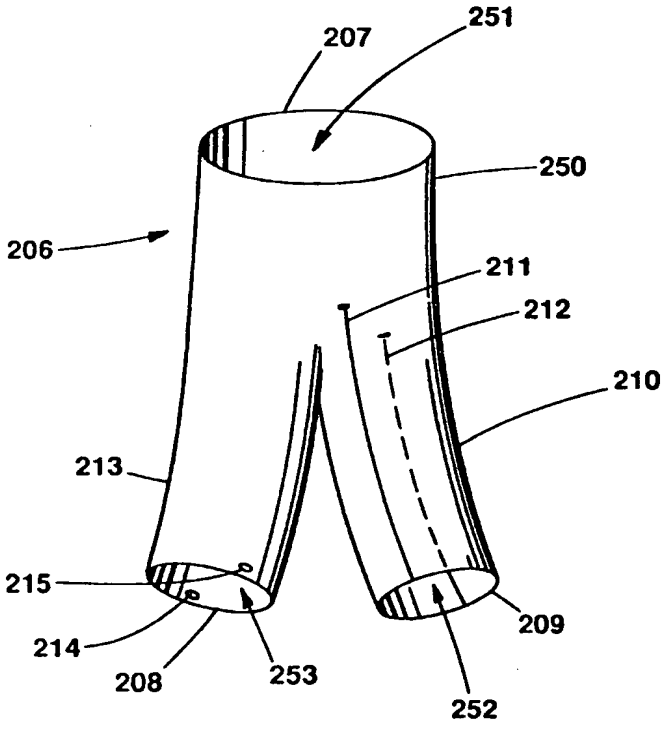
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Fig. 22

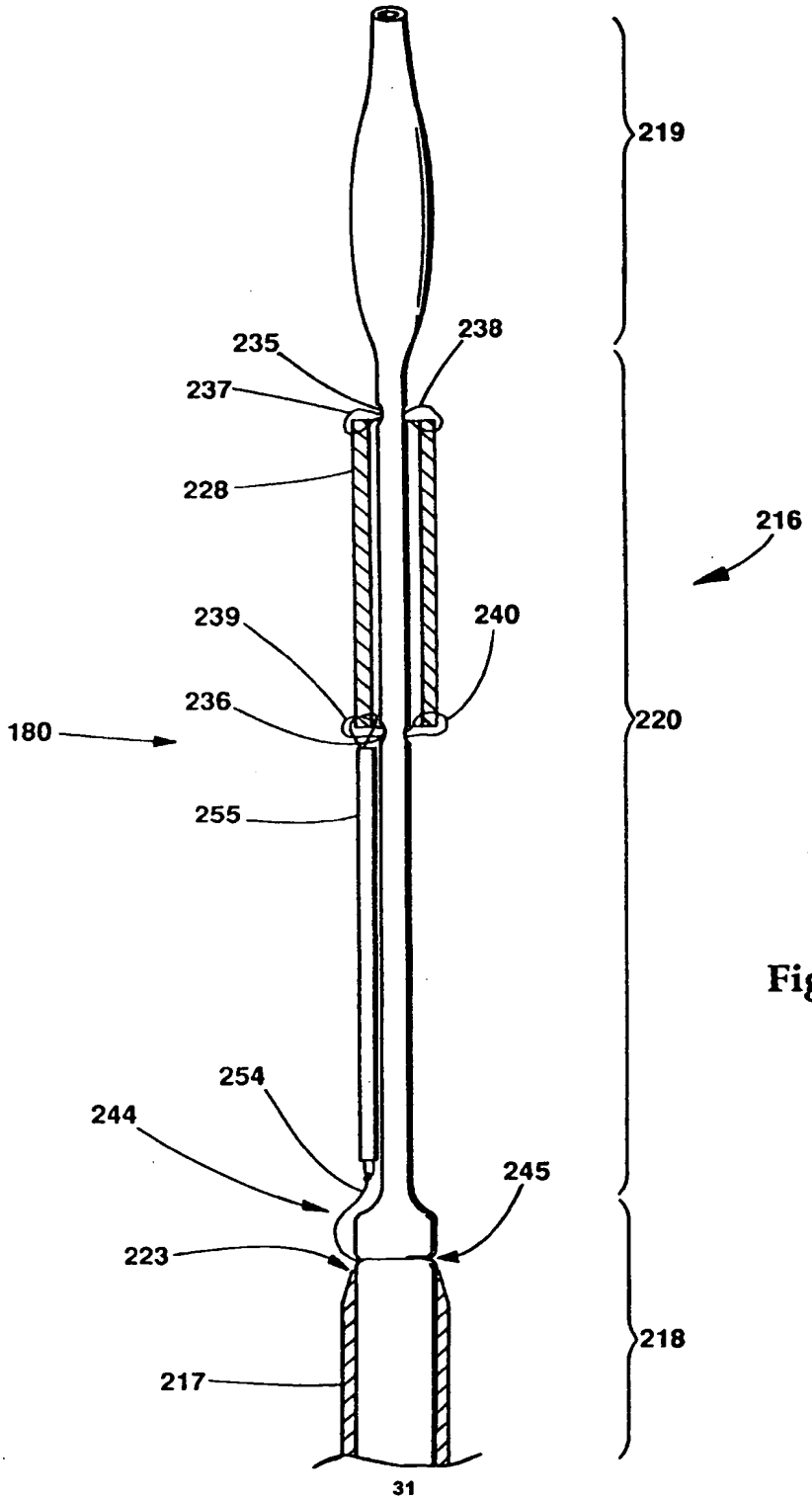
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Fig. 23

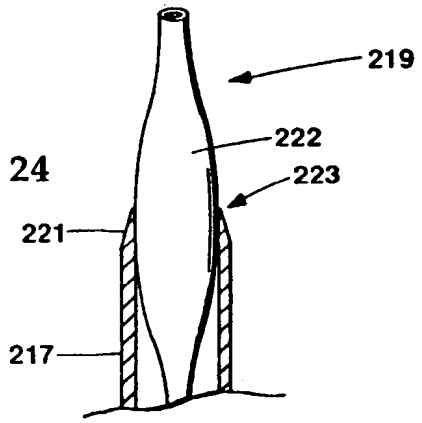


Fig. 24

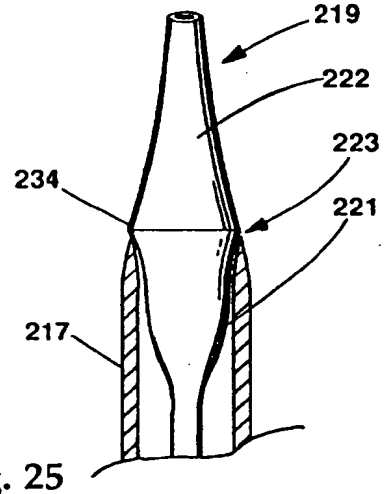


Fig. 25

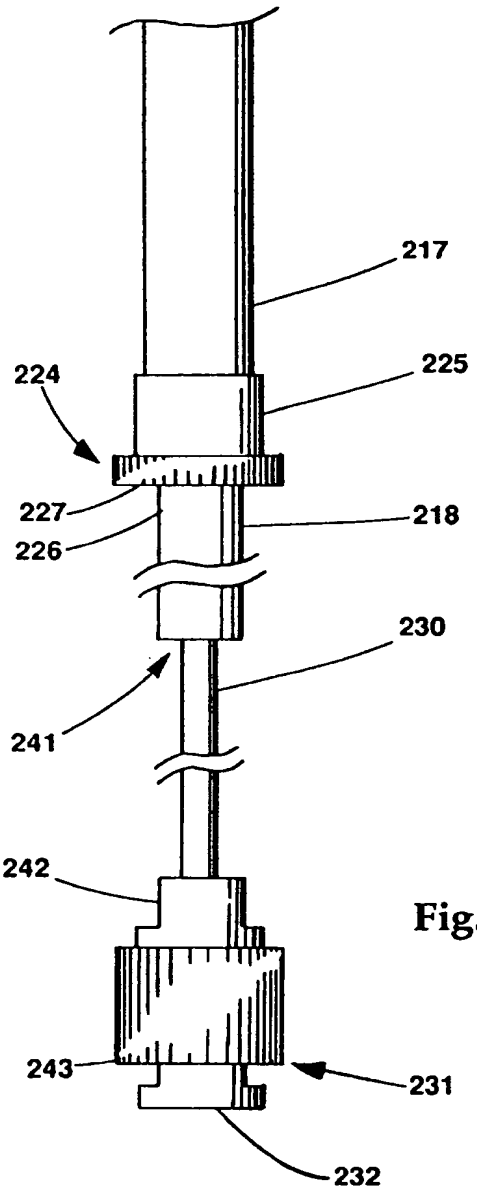


Fig. 26

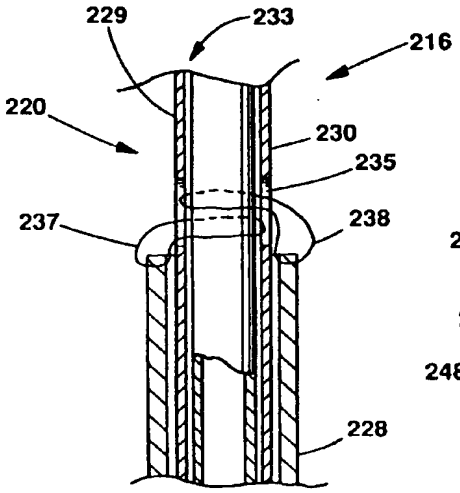


Fig. 27

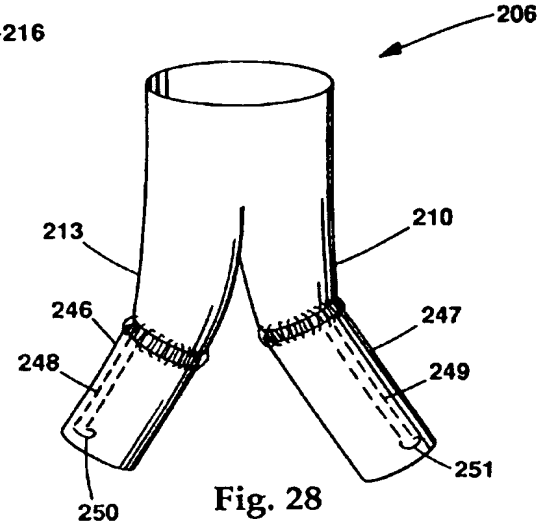


Fig. 28

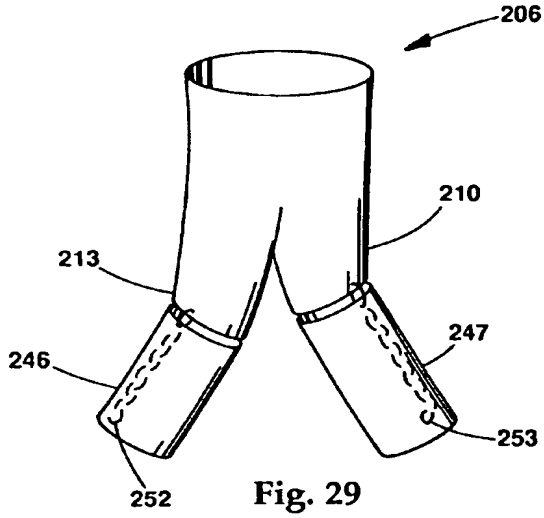


Fig. 29

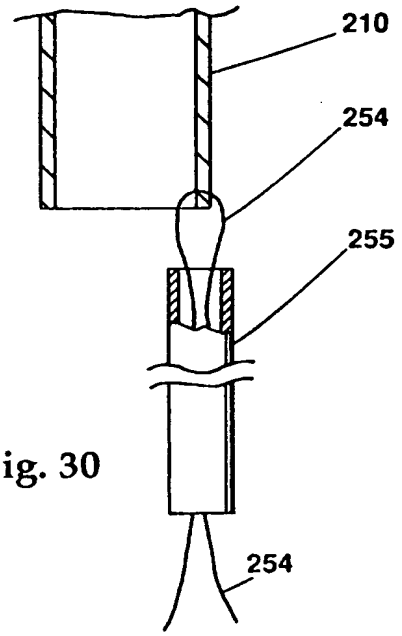


Fig. 30

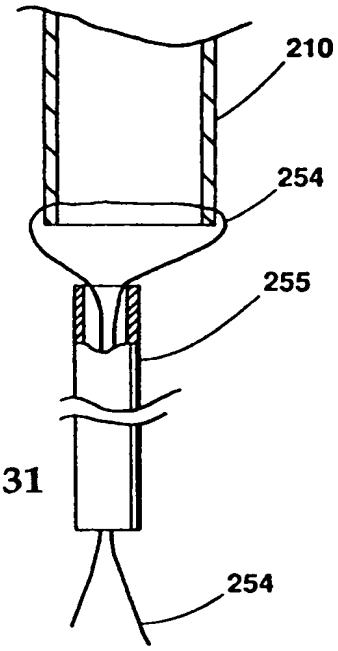


Fig. 31

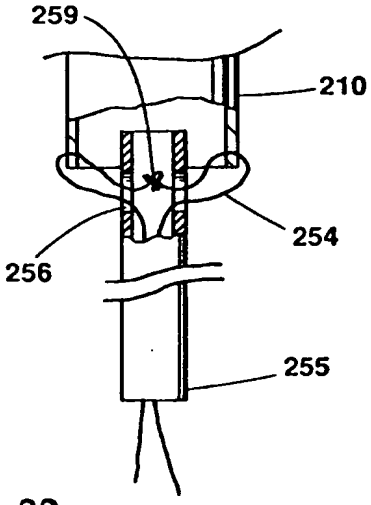
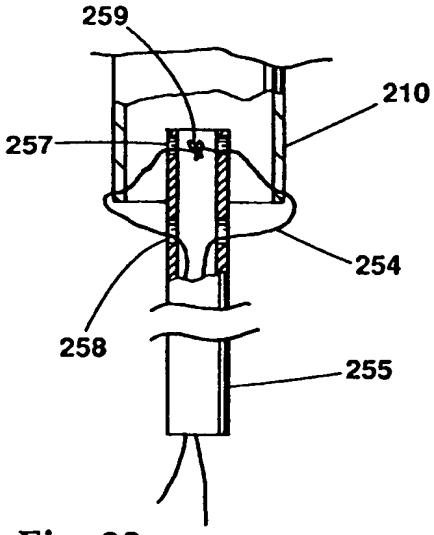


Fig. 32



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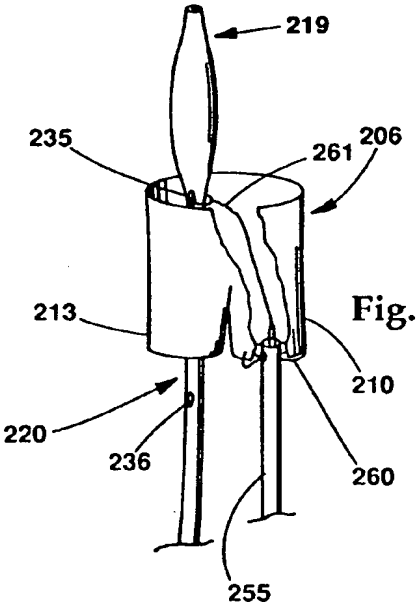


Fig. 34

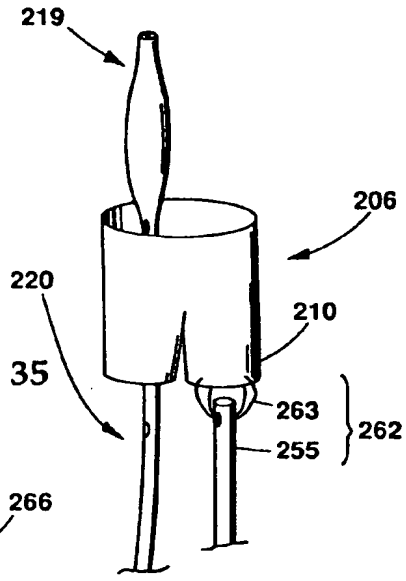


Fig. 35

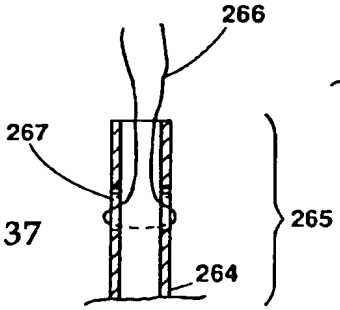


Fig. 37

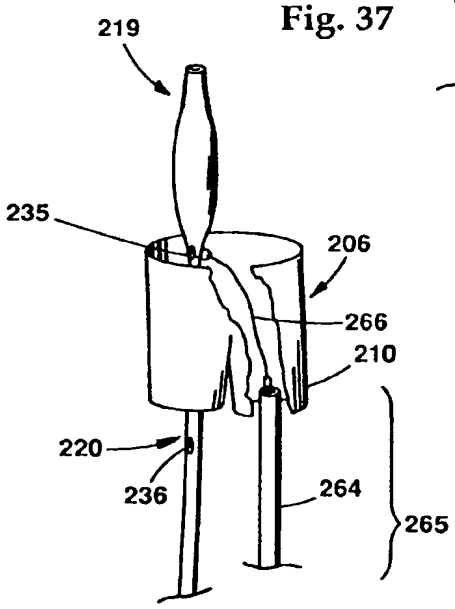


Fig. 36

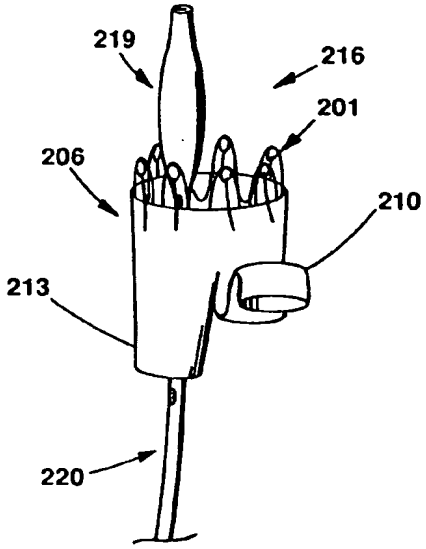


Fig. 38

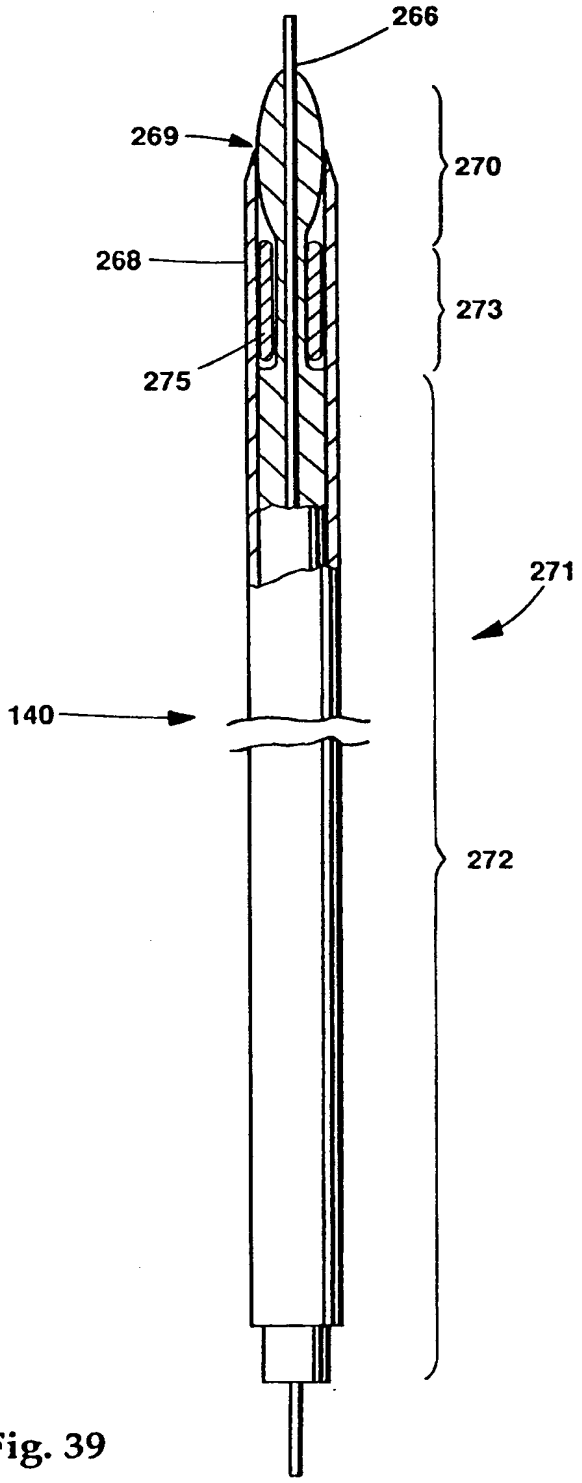


Fig. 39

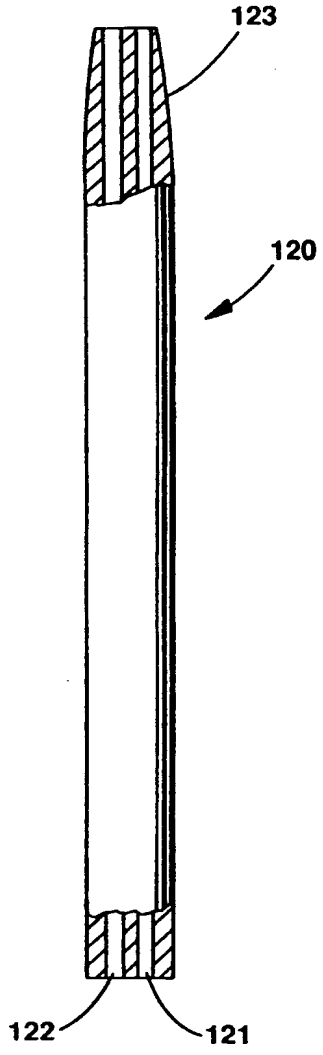


Fig. 42

Fig. 40

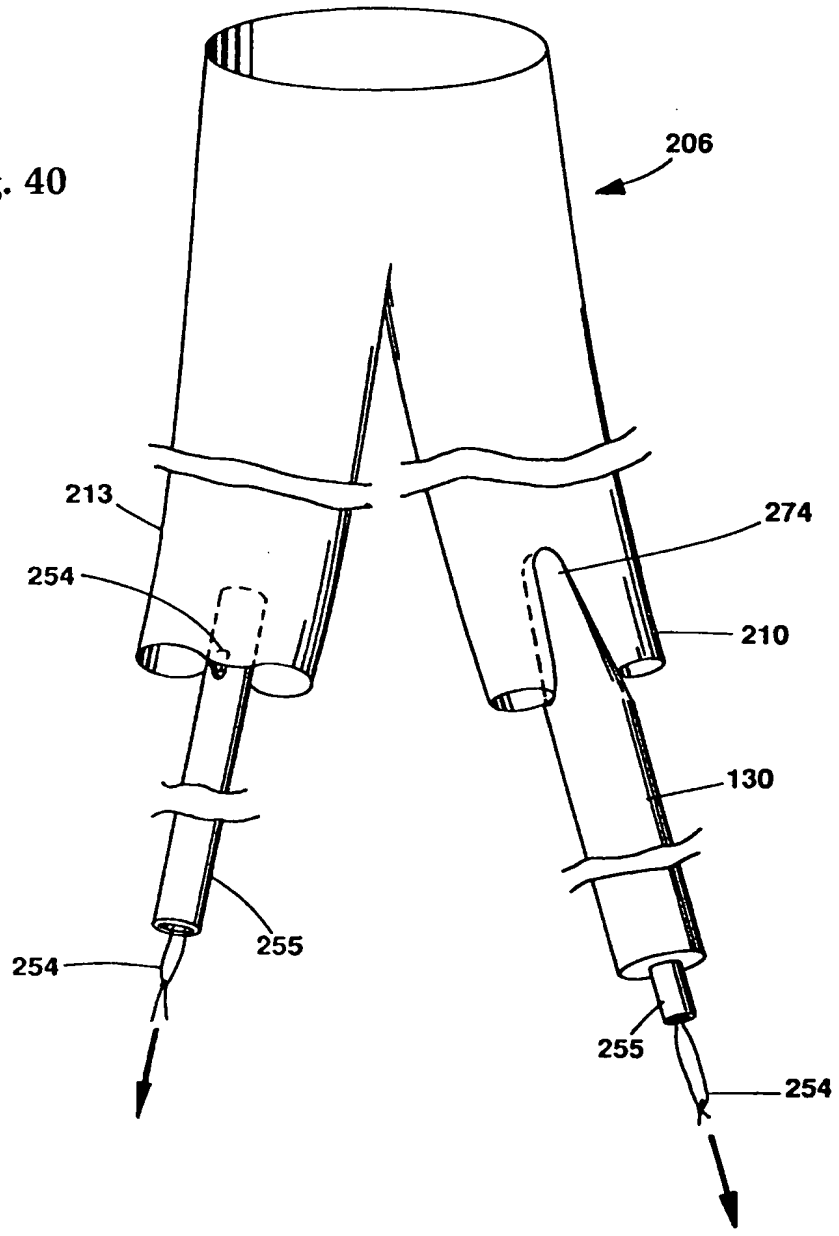
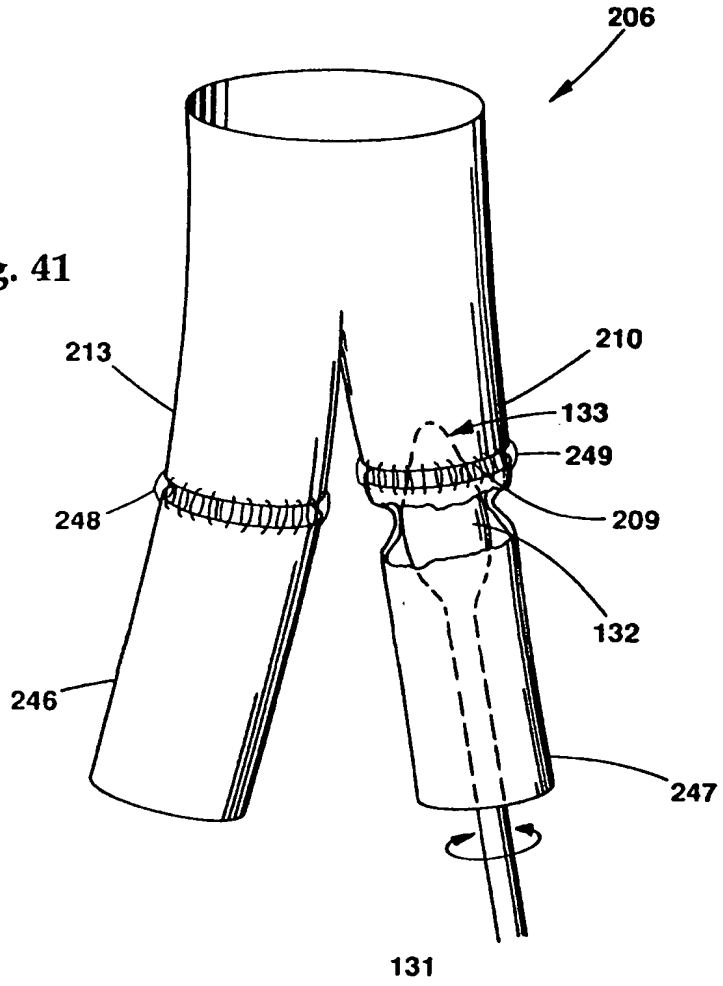


Fig. 41



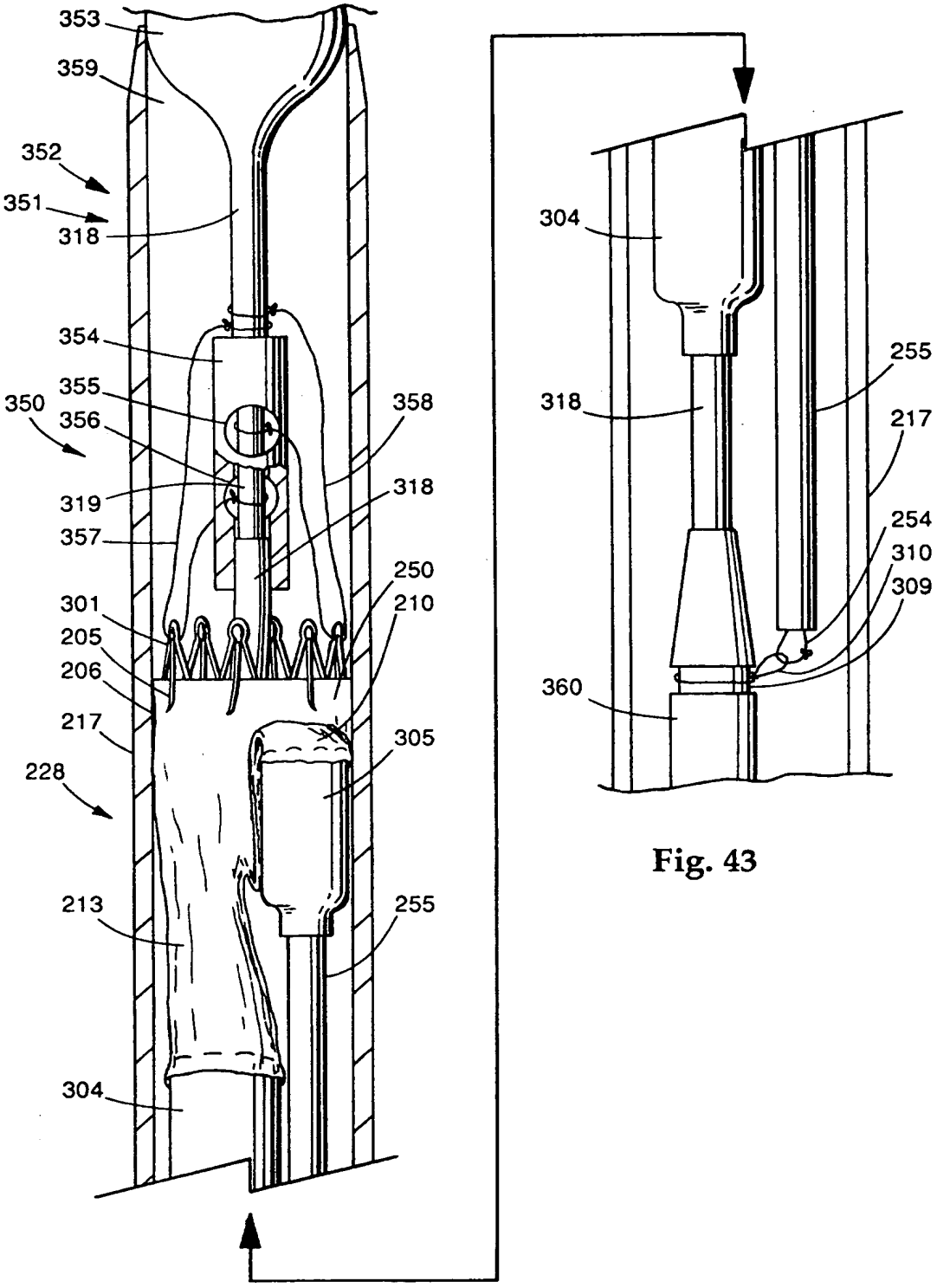

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Fig. 43

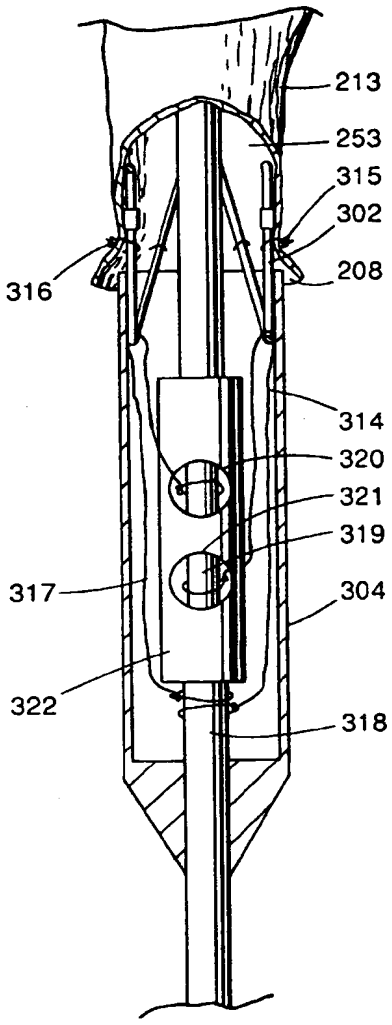
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Fig. 44

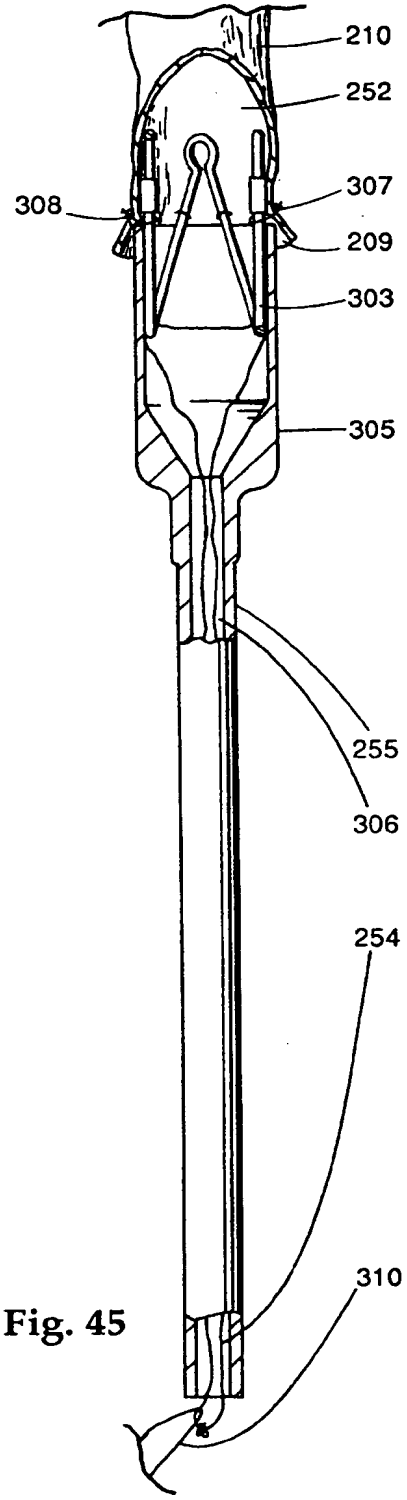
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Fig. 45

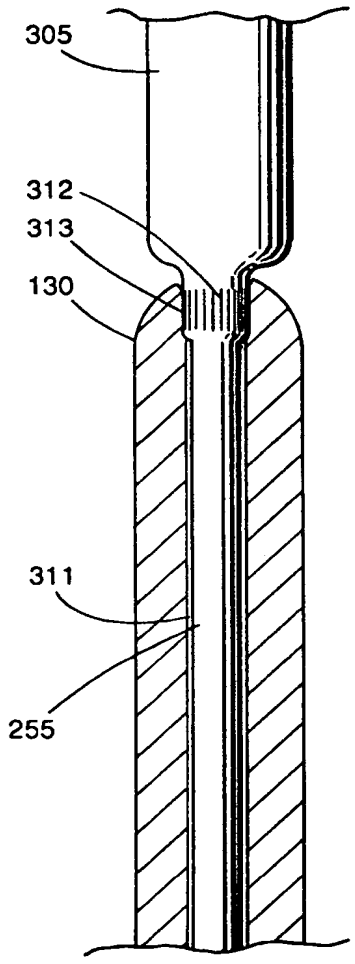

Fig. 46

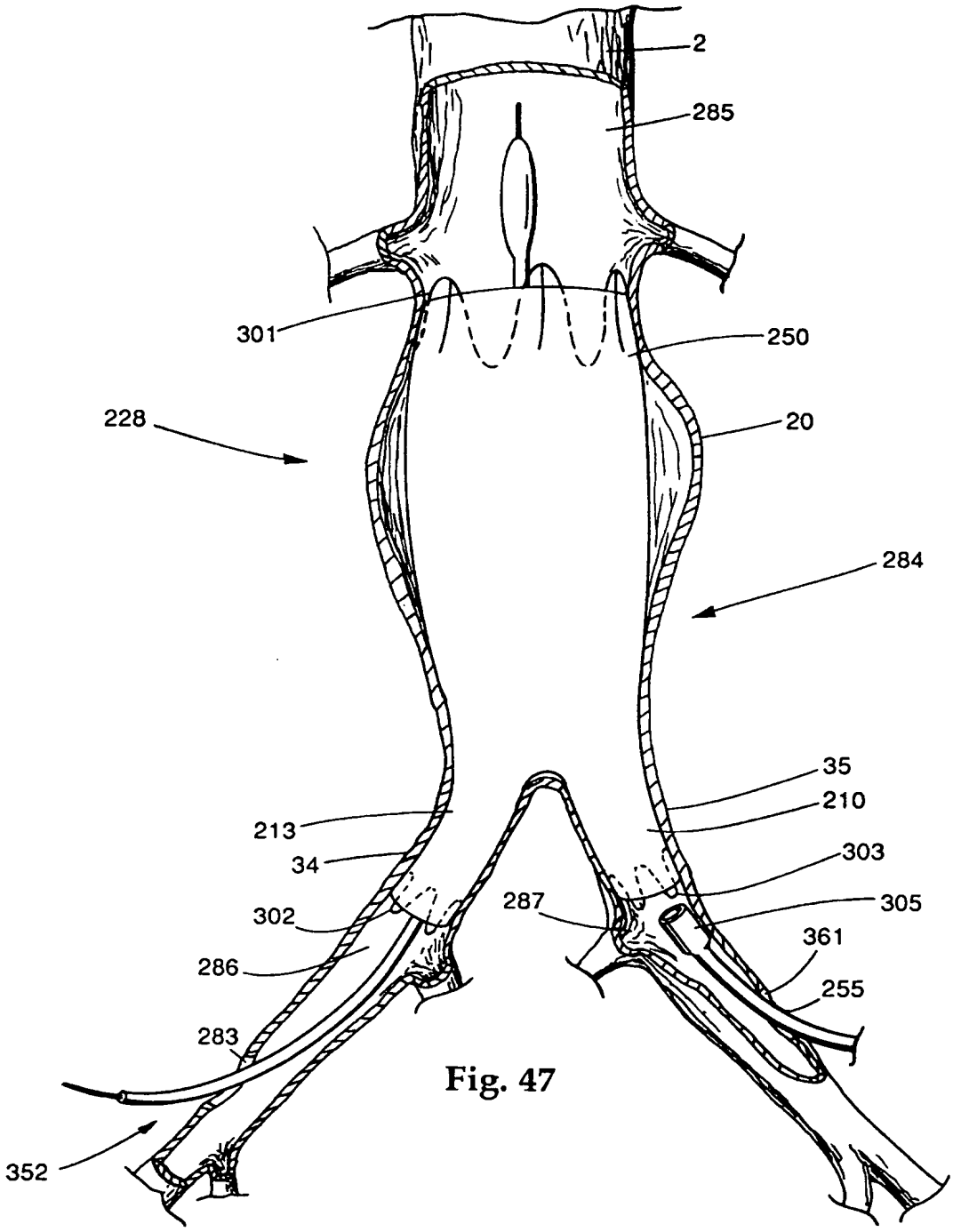
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Fig. 47

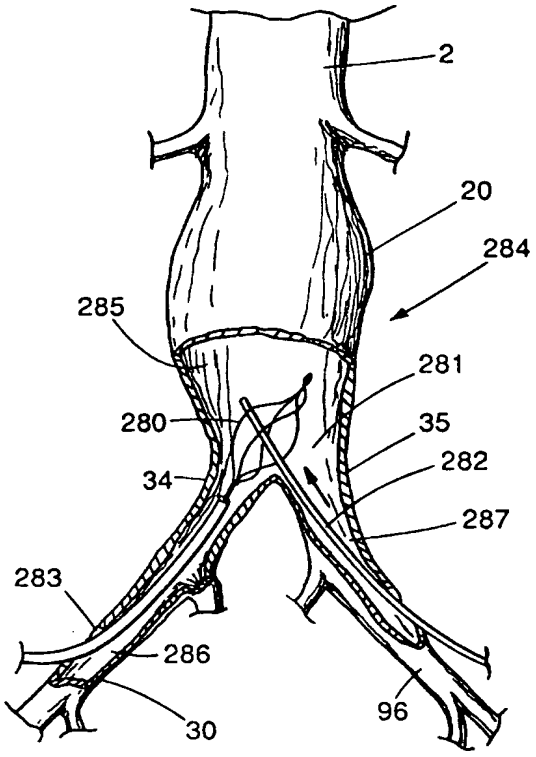
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Fig. 48

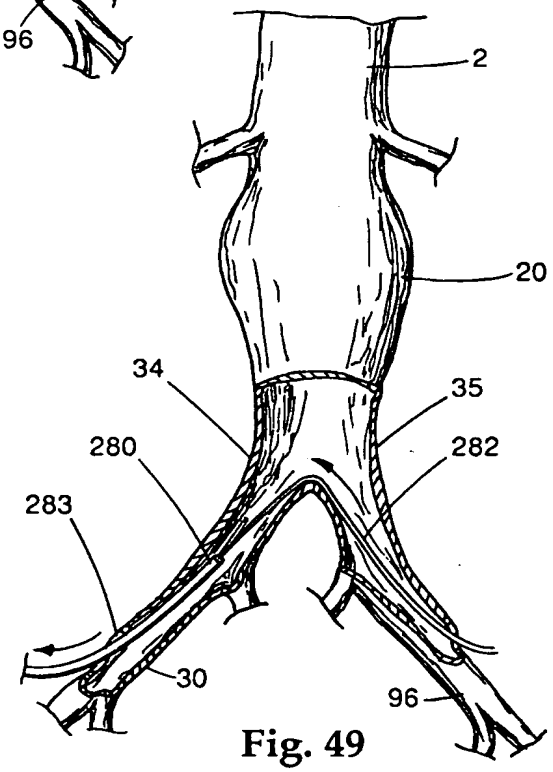
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Fig. 49

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 92 30 9777

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
X,D Y	US-A-4 140 126 (CHOUDHURY) * column 2, line 7 - column 4, line 11; figures * ---	1-5 6-11,13, 14	A61F2/06
X Y	EP-A-0 472 731 (INOUE) * claims 1-4; figures * ---	1,2 6	
X Y	US-A-4 562 596 (KORNBERG) * column 2, line 52 - column 3, line 25; figures * ---	12 7-11,13, 14	
A	EP-A-0 423 916 (GIANTURCO) -----		

TECHNICAL FIELDS SEARCHED (Int. Cl.5)

A61F

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	21 JANUARY 1993	SANCHEZ Y SANCHEZ J.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
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P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
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(54) **Dispositif d'actionnement combiné de deux organes à commande rotative, et chalumeau le comportant**

Vorrichtung zum Zusammenbetätigen von zwei eine rotierende steuerungsenthaltenden Elementen, und Schweissbrenner mit einer solchen Vorrichtung ausgerüstet

Device for controlling together two elements controlled in a rotary way, and nozzle equipped with such a device

(84) Etats contractants désignés:
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(56) Documents cités:
DE-A- 2 051 330
DE-C- 830 277
US-A- 4 949 753

EP 0 744 237 B1

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Description

[0001] La présente invention concerne un dispositif d'actionnement combiné de deux organes à commande rotative.

[0002] Le document US-A-4 949 753, qui représente l'état de la technique le plus proche, décrit un tel dispositif comportant deux roues de commande associées respectivement aux deux organes à commande rotative, et une troisième roue d'actionnement qui coopère simultanément avec les deux roues de commande, laquelle troisième roue est montée déplaçable en rotation sous l'action de moyens de manoeuvre.

[0003] L'invention concerne en outre un chalumeau comportant un tel dispositif.

[0004] Les chalumeaux comportent de manière classique deux vannes associées respectivement à une conduite d'alimentation en combustible et à une conduite d'alimentation en comburant. Ces deux gaz sont typiquement l'acétylène et l'oxygène. Chaque vanne est munie d'une poignée de manoeuvre qui permet le réglage du débit de l'un des gaz combustible et comburant. Cet agencement oblige l'opérateur à actionner les poignées l'une après l'autre.

[0005] Les deux vannes étant indépendantes, et possédant des organes de manoeuvre distincts, leur manipulation est relativement longue.

[0006] Le réglage de la flamme du chalumeau est en outre rendu difficile par le fait que l'opérateur doit régler à la fois le débit total du gaz en sortie du chalumeau et la proportion des gaz combustible et comburant dans le mélange de sortie.

[0007] La présente invention a pour but de permettre l'actionnement de deux organes à commande rotative, notamment deux vannes de commande de chalumeaux, à partir d'un dispositif unique manipulable d'une seule main, permettant le réglage combiné et simultané de la proportion de chaque gaz dans le mélange de sortie et du débit total des gaz.

[0008] A cet effet, l'invention a pour objet un dispositif d'actionnement combiné de deux organes à commande rotative, caractérisé en ce qu'il comporte deux roues de commande associées respectivement aux deux organes à commande rotative, les deux roues étant montées déplaçables en rotation indépendamment l'une de l'autre autour d'un même axe, et en ce qu'il comporte une troisième roue d'actionnement dont l'axe est concourant à l'axe des deux roues de commande et qui coopère simultanément avec les deux roues de commande, laquelle troisième roue est montée déplaçable en rotation, sous l'action de moyens de manoeuvre, d'une part autour de son propre axe, pour entraîner les deux roues de commande en sens inverses, et d'autre part autour de l'axe de rotation des deux roues de commande suivant un arc de cercle pour entraîner celles-ci dans un même sens.

[0009] Suivant des modes particuliers de réalisation, le dispositif d'actionnement peut présenter l'une ou plusieurs des caractéristiques suivantes :

- les roues de commande sont des engrenages coniques,
- les deux roues de commande ont des diamètres sensiblement égaux et l'axe de rotation de la roue d'actionnement est sensiblement perpendiculaire à l'axe de rotation des deux roues de commande,
- chaque roue de commande est fixée à l'extrémité d'un arbre, libre en rotation dans un alésage d'un châssis de support,
- les moyens de manoeuvre de la roue d'actionnement comportent une tige à une extrémité de laquelle est fixée la roue d'actionnement et à l'autre extrémité de laquelle est prévue une poignée de manoeuvre,
- la tige est montée déplaçable suivant un arc de cercle dans une lumière de guidage ménagée dans une paroi cylindrique,
- la tige comporte une butée radiale et il est prévu au moins une rampe disposée le long de la surface balayée par la tige, et adaptée pour coopérer avec la butée pour limiter le débattement angulaire de la roue d'actionnement autour de son axe en fonction de la position angulaire de celle-ci autour de l'axe des roues de commande,
- le dispositif comporte deux rampes disposées de part et d'autre de la tige et ayant des profils différents,
- la butée a une forme sensiblement elliptique,
- les organes à commande rotative sont des vannes de commande de l'écoulement de gaz,
- les sens de commande des vannes sont identiques lorsque les roues de commande sont entraînées dans un même sens;

L'invention concerne également un chalumeau comportant un dispositif d'actionnement combiné tel que décrit précédemment, adapté pour actionner deux vannes de commande de l'écoulement de deux gaz d'alimentation.

[0010] L'invention sera mieux comprise à la lecture de la description qui va suivre, donnée uniquement à titre d'exemple et faite en se référant aux dessins, sur lesquels :

- la Fig.1 est une vue de face, partiellement en coupe, du dispositif d'actionnement selon l'invention;
- la Fig.2 est une vue en coupe suivant la ligne II-II du dispositif de la figure 1; et
- les Fig.3 et 4 sont des vues développées schématiques explicitant le fonctionnement d'une partie du dispositif d'actionnement suivant deux variantes de réalisation de celui-ci.

[0011] Le dispositif d'actionnement combiné, repré-

senté sur les figures 1 et 2, comporte essentiellement un châssis 10 sur lequel sont fixées deux vannes à commande rotative analogues 12 et 14 disposées en vis à vis suivant un même axe X-X. Ces vannes sont supposées commander l'écoulement de deux gaz d'alimentation d'un chalumeau, non représenté.

[0012] Chaque vanne de commande 12,14 comporte une roue de commande 16,18 reçue à l'intérieur du châssis 10 et coopérant avec une roue d'actionnement 20 schématisée sur la figure 1. La roue 20 est associée à des moyens de manoeuvre 22 représentés sur la figure 2.

[0013] Le châssis 10 présente une forme générale cylindrique. Il est muni d'une chambre centrale 24 délimitée par deux flasques 26,28 reliés par une paroi latérale cylindrique 29. La chambre centrale 24 est ouverte sur l'extérieur par une lumière 30 de guidage des moyens de manoeuvre 22. Cette lumière 30 est ménagée transversalement dans la paroi cylindrique 29 et s'étend sur 180°.

[0014] Deux nervures extérieures 32,34 disposées de part et d'autre de la lumière 30 définissent deux rampes 32A, 34A en arc de cercle disposées en vis à vis le long de la lumière 30.

[0015] Le châssis 10 est fixé sur un bâti 36, par exemple d'une installation d'alimentation en gaz du chalumeau par deux colliers 38 munis de vis de fixation 40.

[0016] Les vannes 12,14 sont analogues et seule la vanne 12 sera décrite en regard de la figure 1.

[0017] Cette dernière comporte un corps de vanne 42 vissé à travers un trou débouchant taraudé 44 d'axe X-X ménagé au centre du flasque 26. Le corps 42 présente un passage axial 46 ayant une extrémité avant 48 de plus faible diamètre débouchant dans la chambre 24.

[0018] Un arbre 50, muni à son extrémité arrière d'un rebord périphérique 52, est emmanché dans le conduit 46 et fait saillie par son extrémité avant 48 dans la chambre 24. La roue 16, formée par un engrenage conique, est fixée à l'extrémité avant de l'arbre 50 à l'intérieur de la chambre 24 à l'aide d'une goupille 56 et d'une vis 58. Une rondelle 60 est interposée entre la roue 16 et le corps de vanne 42 afin de faciliter la rotation de la roue 16 par rapport à celui-ci.

[0019] Un alésage borgne taraudé 62 débouche à l'extrémité arrière de l'arbre 50. Un coulisseau 64 de forme générale cylindrique est logé à l'intérieur du conduit 46 en arrière de l'arbre 50. L'extrémité avant filetée 66 de celui-ci est reçue à l'intérieur de l'alésage taraudé 62.

[0020] Une gorge longitudinale 68 est ménagée dans le corps du coulisseau. Elle reçoit l'extrémité d'un doigt radial 70 solidaire du corps 42 et adapté pour immobiliser en rotation le coulisseau 64. Par ailleurs, ce dernier est muni à son extrémité arrière d'une gorge circulaire dans laquelle est reçu un joint d'étanchéité 72.

[0021] A son extrémité arrière, le coulisseau 64 comporte une tige d'actionnement 74 dont l'extrémité arrière coopère avec une valve 76 fixée à l'arrière du conduit 46 par un adaptateur 78.

[0022] La valve 76 forme une entrée de la vanne 12, et est adaptée pour régler le passage du gaz vers une chambre de sortie 80 délimitée par le conduit 46, en fonction du déplacement de la tige d'actionnement 74. Cette chambre de sortie 80 est reliée, par un passage radial 82 muni d'un raccord 84, à une conduite d'alimentation du chalumeau non représentée.

[0023] Les vannes 12 et 14 sont analogues, et les sens de filetage des extrémités filetées 66 sont adaptés pour que les sens de commande des vannes soient identiques lorsque les roues de commande 16 et 18 sont entraînées dans un même sens. On suppose ici que lorsque les roues 16 et 18 sont entraînées dans le sens des flèches F1 et F2, les vannes 12 et 14 se ferment.

[0024] Les moyens de manoeuvre 22 représentés sur la figure 2 comportent une tige d'actionnement 84 traversant la lumière 30 et dont l'axe Y-Y est concourant à l'axe X-X des roues 16 et 18. Elle est maintenue perpendiculairement à l'axe X-X par deux tampons 86 et 88 disposés en appui de part et d'autre de la paroi 29 le long de la lumière 30.

[0025] La roue d'actionnement 20 est fixée par tout moyen approprié, une goupille par exemple, à l'extrémité de la tige 84. Elle est formée d'un pignon conique, dont la couronne dentée coopère simultanément avec les couronnes dentées des roues 16 et 18.

[0026] A son autre extrémité, la tige 84 comporte une poignée de manoeuvre 90 fixée par un écrou 92.

[0027] Entre le tampon 88 et la poignée 90, la tige 84 porte une butée 94 de forme générale elliptique perpendiculaire à la tige et solidaire de celle-ci en rotation. Cette butée, qui est adaptée pour coopérer avec les rampes 32A, 34A, est maintenue contre le tampon 88 par un écrou 96. Deux modes de réalisation de la butée 94 et des rampes 32A, 34A seront décrits en détail en regard des figures 3 et 4.

[0028] Le dispositif de commande représenté sur la figure 1 est destiné à l'alimentation d'un chalumeau de chauffe. La vanne 12 est associée à une conduite d'alimentation en combustible, alors que la vanne 14 est associée à une conduite d'alimentation en comburant.

[0029] On conçoit que le déplacement angulaire de la roue d'actionnement 20 autour de son axe Y-Y dans le sens de la flèche F3, entraîne en rotation la roue 16 dans le sens opposé à celui de la flèche F1 et la roue 18 dans le sens de la flèche F2. La vanne 12 est alors progressivement ouverte alors que la vanne 14 est progressivement fermée.

[0030] Ainsi, il est possible, par rotation de la poignée 90 autour de l'axe Y-Y, de modifier la composition du mélange obtenu en sortie du chalumeau par ouverture d'une vanne et fermeture simultanée de l'autre vanne, ceci par exemple en maintenant le débit total de gaz à une valeur sensiblement constante.

[0031] Par ailleurs, en déplaçant la poignée 90 dans le sens de la flèche F4 autour de l'axe X-X et suivant la

lumière 30, la roue d'actionnement 20 entraîne les roues de commande 16 et 18 dans le même sens, dans le sens opposé aux flèches F1 et F2 sur les figures 1 et 2. Les vannes 12 et 14 sont alors progressivement ouvertes, ce qui accroît le débit total du mélange obtenu en sortie du chalumeau, les proportions en gaz combustible et comburant restant sensiblement inchangées.

[0032] Il est ainsi possible de régler le débit total de sortie en positionnant correctement la poignée 90 le long de la lumière de guidage 30.

[0033] Sur les figures 3 et 4, est schématisée une vue développée de deux modes de réalisation des rampes 32A, 34A. La tige 84 associée à la butée 94 est représentée dans diverses positions possibles de celles-ci.

[0034] Dans le mode de réalisation représenté sur la figure 3, les rampes 32A et 34A sont symétriques par rapport à un axe Z-Z de la lumière 30. Elles délimitent ainsi entre elles un canal s'élargissant d'un tronçon d'extrémité étroit 102 à un tronçon d'extrémité élargi 104, reliés par un tronçon intermédiaire 106 de largeur progressivement croissante. Le tronçon 104 est supposé correspondre aux débits de sortie élevés et le tronçon 102 aux débits faibles.

[0035] La butée 94 qui s'étend entre les deux rampes 32A, 34A a une forme allongée sensiblement symétrique, et son contour délimite une ellipse. L'axe de l'arbre 84 passe par le centre de cette ellipse.

[0036] Dans ces conditions, on comprend que lorsque la butée 94 est située dans le tronçon 102, le petit axe de l'ellipse est maintenue entre les rampes 32A, 34A, interdisant la rotation de la roue 20 autour de l'axe Y-Y.

[0037] Par contre, lorsque la butée 94 est disposée dans le tronçon intermédiaire 106, un débattement angulaire α de la roue 20 est possible autour de l'axe Y-Y avant que la butée 94 ne soit en contact avec l'une des rampes 32A et 34A, comme cela est représenté sur la figure 3.

[0038] Lorsque la butée 94 est dans le tronçon 104, la butée 94 est libre de tourner autour de l'axe Y-Y sans entrer en contact avec l'une ou l'autre des rampes 32A, 34A.

[0039] Les rampes 32A, 34A limitent ainsi le débattement angulaire de la roue de commande 20 autour de son axe Y-Y en fonction de la position angulaire de celle-ci autour de l'axe X-X. De ce fait, en fonction de la position de la poignée 90 par rapport à la lumière 30, et donc en fonction du débit total de gaz, la largeur de la plage de réglage de la composition du mélange en sortie du chalumeau est plus ou moins étendue.

[0040] Tel que représenté sur la figure 3, plus le débit total de gaz est grand, plus la largeur de la plage de réglage de la composition du mélange est grande.

[0041] Par ailleurs, la forme des rampes est adaptée pour maintenir la composition du mélange dans une plage acceptable définie par des contraintes de sécurité ou liée au procédé dans lequel le chalumeau est utilisé. De plus, cet agencement, grâce au tronçon 102, permet un préréglage du mélange à l'allumage et à l'extinction du chalumeau, évitant ainsi la production de claquements et de flammèches.

[0042] En variante, comme cela est représenté sur la figure 4, il est possible de limiter de façon différenciée l'ouverture ou la fermeture des deux vannes. Dans ce cas, les rampes 32A et 34A sont dissymétriques par rapport à l'axe Z-Z de la lumière 30.

[0043] Dans l'exemple représenté, la rampe 32A présente un profil plus aplati que celui de la rampe 34A. Par ailleurs, l'axe Y-Y de la tige 94 est décalé, le long du grand axe de l'ellipse 94, par rapport au centre de celle-ci.

[0044] Cet agencement assure une réduction de la plage de réglage potentiel des deux gaz dans des domaines opposés. Ainsi, tel que représenté sur la figure 4, la fermeture de la vanne 12 est plus limitée que celle de la vanne 14, et, inversement, l'ouverture de la vanne 14 est plus limitée que celle de la vanne 12.

[0045] On conçoit que bien d'autres profils sont possibles pour les rampes 32A et 34A suivant la plage de compositions que l'on souhaite définir pour le mélange en sortie du chalumeau en fonction du débit total des gaz. Par ailleurs, l'une des deux rampes peut être supprimée. De plus, la butée 94 peut avoir toute autre forme appropriée qu'une forme d'ellipse.

[0046] Dans le mode de réalisation représenté, les sens de commande des vannes 12 et 14 sont identiques lorsque les roues de commande sont entraînées dans un même sens. En variante, par inversion du sens de filetage de l'un des coulisseaux, les sens de commande des vannes sont opposés lorsque les roues de commande sont entraînées dans un même sens. Dans ces conditions, le débit total de gaz en sortie du chalumeau est commandé en tournant la poignée 90 autour de son axe Y-Y alors que la composition du mélange en sortie est commandée par déplacement de cette même poignée le long de la lumière 30.

[0047] De plus, il est possible d'utiliser des vannes dont l'ouverture dépend de la position angulaire de la roue de commande associée suivant une loi prédéterminée, non linéaire. Une telle vanne peut être obtenue par utilisation d'un pointeau coulissant assujetti à une surface de came liée à la roue de commande et dont le profil correspond à la loi de commande d'ouverture souhaitée.

[0048] Suivant une autre variante, les roues de commande peuvent avoir des nombres de dents différents sur leur surface d'entraînement et des diamètres différents. Dans ce cas, l'axe Y-Y de rotation de la roue d'actionnement n'est plus orthogonal à l'axe X-X des roues de commande, mais il reste concourant à celui-ci.

Revendications

1. Dispositif d'actionnement combiné de deux organes (10,12) à commande rotative, comportant deux roues (16,18) de commande associées respectivement aux deux organes (10,12) à commande rota-

tive, les deux roues étant montées déplaçables en rotation indépendamment l'une de l'autre autour d'un même axe (X-X), et une troisième roue d'actionnement (20) dont l'axe est concourant à l'axe (X-X) des deux roues de commande (16,18) et qui coopère simultanément avec les deux roues de commande (16,18), laquelle troisième roue (20) est montée déplaçable en rotation, sous l'action de moyens de manoeuvre (22), d'une part autour de son propre axe (Y-Y), pour entraîner les deux roues de commande (16,18) en sens inverses, et d'autre part autour de l'axe de rotation (X-X) des deux roues de commande (16,18) suivant un arc de cercle pour entraîner celles-ci dans un même sens.

2. Dispositif selon la revendication 1, caractérisé en ce que les roues de commande (16,18) sont des engrenages coniques.

3. Dispositif selon la revendication 1 ou 2, caractérisé en ce que les deux roues de commande (16,18) ont des diamètres sensiblement égaux et l'axe de rotation (Y-Y) de la roue d'actionnement (20) est sensiblement perpendiculaire à l'axe (X-X) de rotation des deux roues de commande (16,18).

4. Dispositif selon l'une quelconque des revendications précédentes, caractérisé en ce que chaque roue de commande (16,18) est fixée à l'extrémité d'un arbre (50), libre en rotation dans un alésage (48) d'un châssis de support (10).

5. Dispositif selon l'une quelconque des revendications précédentes, caractérisé en ce que les moyens de manoeuvre (22) de la roue d'actionnement (20) comportent une tige (84) à une extrémité de laquelle est fixée la roue d'actionnement (20) et à l'autre extrémité de laquelle est prévue une poignée de manoeuvre (90).

6. Dispositif selon la revendication 5, caractérisé en ce que la tige (84) est montée déplaçable suivant un arc de cercle dans une lumière de guidage (30) ménagée dans une paroi cylindrique (29).

7. Dispositif selon la revendication 5 ou 6, caractérisé en ce que la tige (84) comporte une butée radiale (94) et en ce qu'il est prévu au moins une rampe (32A, 34A) disposée le long de la surface balayée par la tige (84), et adaptée pour coopérer avec la butée (94) pour limiter le débattement angulaire de la roue d'actionnement (20) autour de son axe (Y-Y) en fonction de la position angulaire de celle-ci autour de l'axe (X-X) des roues de commande (16,18).

8. Dispositif selon la revendication 7, caractérisé en ce qu'il comporte deux rampes (32A, 34A) disposées de part et d'autre de la tige (84) et ayant des profils différents.

9. Dispositif selon la revendication 7 ou 8, caractérisé en ce que la butée (94) a une forme sensiblement elliptique.

10. Dispositif selon l'une quelconque des revendications précédentes, caractérisé en ce que les organes à commande rotative sont des vannes (12,14) de commande de l'écoulement de gaz.

11. Dispositif selon la revendication 10, caractérisé en ce que les sens de commande des vannes (10,12) sont identiques lorsque les roues de commande (16,18) sont entraînées dans un même sens.

12. Chalumeau comportant un dispositif d'actionnement combiné de deux vannes (12,14) de commande de l'écoulement de deux gaz d'alimentation selon la revendication 10 ou 11.

Claims

1. Device for the combined activation of two elements (10, 12) with rotary control, the said device having two control wheels (16, 18) respectively associated with the two elements (10, 12) with rotary control, the two wheels being mounted so as to be displaceable in rotation, independently of one another, about the same axis (X-X), and a third activating wheel (20), the axis of which is convergent with the axis (X-X) of the two control wheels (16, 18) and which simultaneously interacts with the said two control wheels (16, 18), which third wheel (20) is mounted so as to be displaceable in rotation, under the action of manoeuvring means (22), on the one hand about its own axis (Y-Y) in order to drive the two control wheels (16, 18) in opposite directions, and on the other hand about the axis of rotation (X-X) of the two control wheels (16, 18) along a circular arc in order to drive the said control wheels in the same direction.

2. Device according to claim 1, characterised in that the control wheels (16, 18) are bevel gears.

3. Device according to claim 1 or 2, characterised in that the two control wheels (16, 18) have substantially equal diameters and the axis of rotation (Y-Y) of the activating wheel (20) is substantially perpendicular to the axis (X-X) of rotation of the two control wheels (16, 18).

4. Device according to any one of the preceding claims, characterised in that each control wheel (16, 18) is fixed to the end of a shaft (50) which is free to rotate in a bore (48) in a supporting frame

(10).

5. Device according to any one of the preceding claims, characterised in that the means (22) for manoeuvring the activating wheel (20) have a rod (84), to one end of which the activating wheel (20) is fixed and on the other end of which a manoeuvring handle (90) is provided.

6. Device according to claim 5, characterised in that the rod (84) is mounted so as to be displaceable along a circular arc in a guiding opening (30) arranged in a cylindrical wall (29).

7. Device according to claim 5 or 6, characterised in that the rod (84) has a radial stop (94) and in that there is provided at least one ramp (32A, 34A) which is disposed along the surface swept by the rod (84) and is adapted to interact with the stop (94) in order to limit the angular clearance of the activating wheel (20) about its axis (Y-Y) in accordance with the angular position of the said wheel about the axis (X-X) of the control wheels (16, 18).

8. Device according to claim 7, characterised in that it has two ramps (32A, 34A) disposed on either side of the rod (84) and having different profiles.

9. Device according to claim 7 or 8, characterised in that the stop (94) has a substantially elliptical shape.

10. Device according to any one of the preceding claims, characterised in that the elements with rotary control are gas flow control valves (12, 14).

11. Device according to claim 10, characterised in that the directions of control of the valves (10, 12) are identical when the control wheels (16, 18) are driven in the same direction.

12. Blowtorch having a device for the combined activation of two valves (12, 14) for controlling the flow of two supply gases, in accordance with claim 10 or 11.

Patentansprüche

1. Vorrichtung zur kombinierten Verstellung von zwei drehbetätigbaren Mitteln (10, 12), umfassend zwei Betätigungsräder (16, 18), die jeweils mit dem entsprechenden drehbetätigbaren Mittel (10, 12) verbunden und voneinander unabhängig drehbar auf derselben Achse (X-X) angeordnet sind, und ein drittes Betätigungsrad (20), dessen Achse sich mit der Achse (X-X) der zwei Betätigungsräder (16, 18) kreuzt und das gleichzeitig auf beide Betätigungsräder (16, 18) einwirkt, welches dritte Rad (20) über Bedienungsmittel (22) einerseits zum gegensinnigen Antrieb der zwei Betätigungsräder (16, 18) um seine eigene Achse (Y-Y) und andererseits entlang eines Kreisbogens um die Drehachse (X-X) der zwei Betätigungsräder (16, 18) drehbar ist, um letztere gleichsinnig anzutreiben.

2. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß die Betätigungsräder (16, 18) Kegelräder sind.

3. Vorrichtung nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß die zwei Betätigungsräder (16, 18) etwa gleiche Durchmesser haben und die Drehachse (Y-Y) des dritten Betätigungsrades (20) ungefähr rechtwinklig zur Drehachse (X-X) der zwei Betätigungsräder (16, 18) steht.

4. Vorrichtung nach einem der vorstehenden Ansprüche, dadurch gekennzeichnet, daß jedes Betätigungsrad (16, 18) am Ende einer Welle (50) sitzt, die in einer Bohrung (48) eines Gestells (10) frei drehbar ist.

5. Vorrichtung nach einem der vorstehenden Ansprüche, dadurch gekennzeichnet, daß die Bedienungsmittel (22) des dritten Betätigungsrades (20) eine Stange (84) umfassen, an deren einem Ende dieses Betätigungsrad (20) sitzt und an deren anderem Ende sich ein Bedienungsgriff (90) befindet.

6. Vorrichtung nach Anspruch 5, dadurch gekennzeichnet, daß die Stange (84) in einem in einer zylindrischen Wand (29) ausgesparten Führungsschlitz (30) entlang eines Kreisbogens verschwenkbar angeordnet ist.

7. Vorrichtung nach Anspruch 5 oder 6, dadurch gekennzeichnet, daß die Stange (84) einen radialen Anschlag (94) aufweist und daß sie mit mindestens einer Führungsbahn (32A, 34A) versehen ist, die entlang der von der Stange (84) bestrichenen Fläche angeordnet ist und mit dem Anschlag (94) zusammenwirkt, so daß der Winkelversatz des dritten Betätigungsrades (20) um seine Achse (Y-Y) in Abhängigkeit von der Winkelstellung derselben bezüglich der Achse (X-X) der Betätigungsräder (16, 18) begrenzt ist.

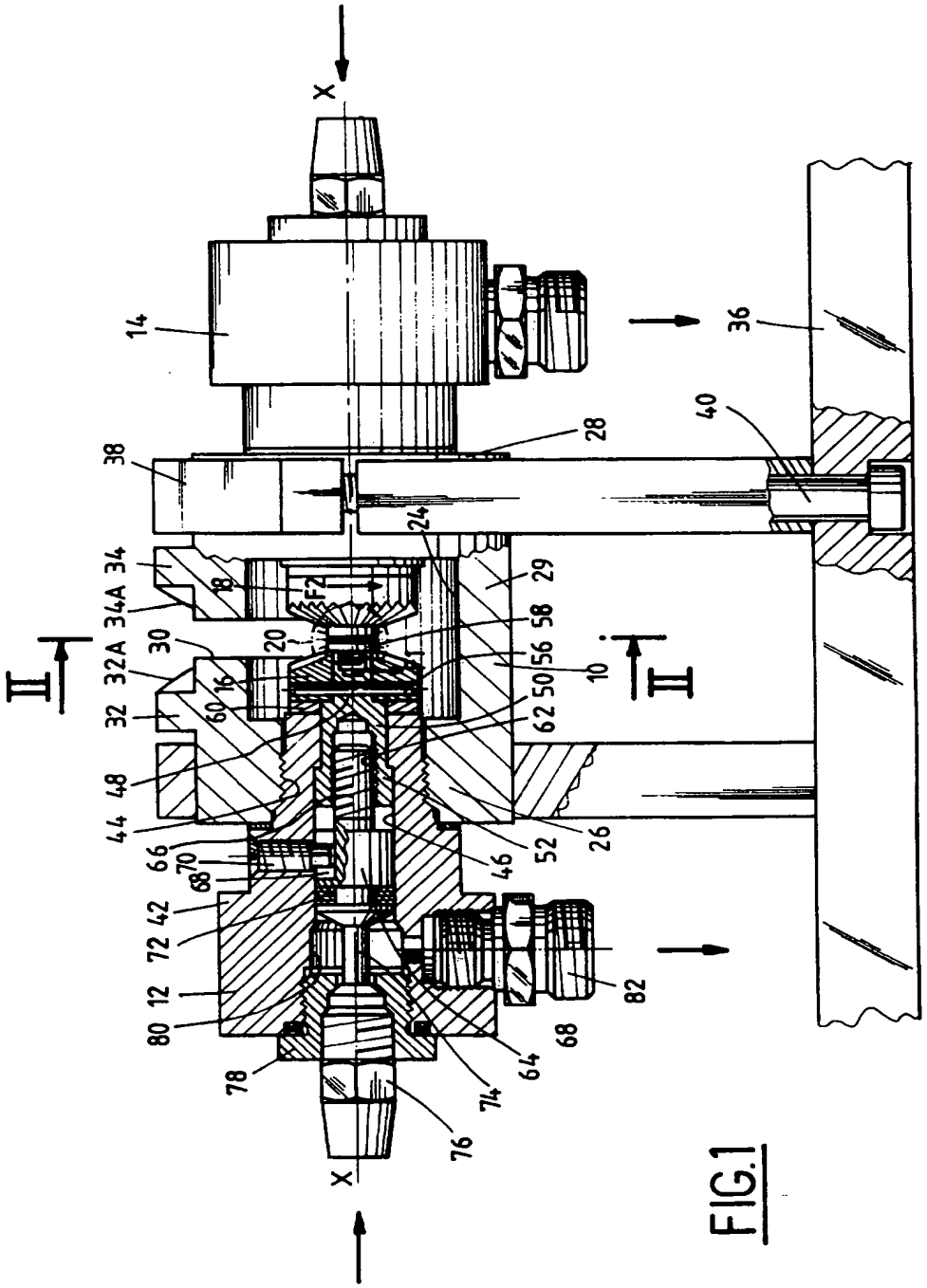
8. Vorrichtung nach Anspruch 7, dadurch gekennzeichnet, daß sie zwei Führungsbahnen (32A, 34A) umfaßt, die beidseits der Stange (84) angeordnet sind und unterschiedliche Profile haben.

9. Vorrichtung nach Anspruch 7 oder 8, dadurch gekennzeichnet, daß der Anschlag (94) eine etwa elliptische Form hat.

10. Vorrichtung nach einem der vorstehenden Ansprüche, dadurch gekennzeichnet, daß die drehbetätigbaren Mittel Steuerventile (12, 14) zur Abgabe von Gas sind.

11. Vorrichtung nach Anspruch 10, dadurch gekennzeichnet, daß die Steuerrichtung der Ventile (10, 12) identisch ist, wenn die Betätigungsräder (16, 18) gleichsinnig angetrieben werden.

12. Schweißbrenner, umfassend eine Vorrichtung zur kombinierten Verstellung von zwei Steuerventilen (12, 14) zur Abgabe von zwei Versorgungsgasen nach Anspruch 10 oder 11.


X
14
36
40
28
38
24
34
34A
18
F2
29
58
30
20
32A
56
10
II
II
32
16
60
50
62
48
44
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80
82
68
64
78
74
76
X

FIG.1

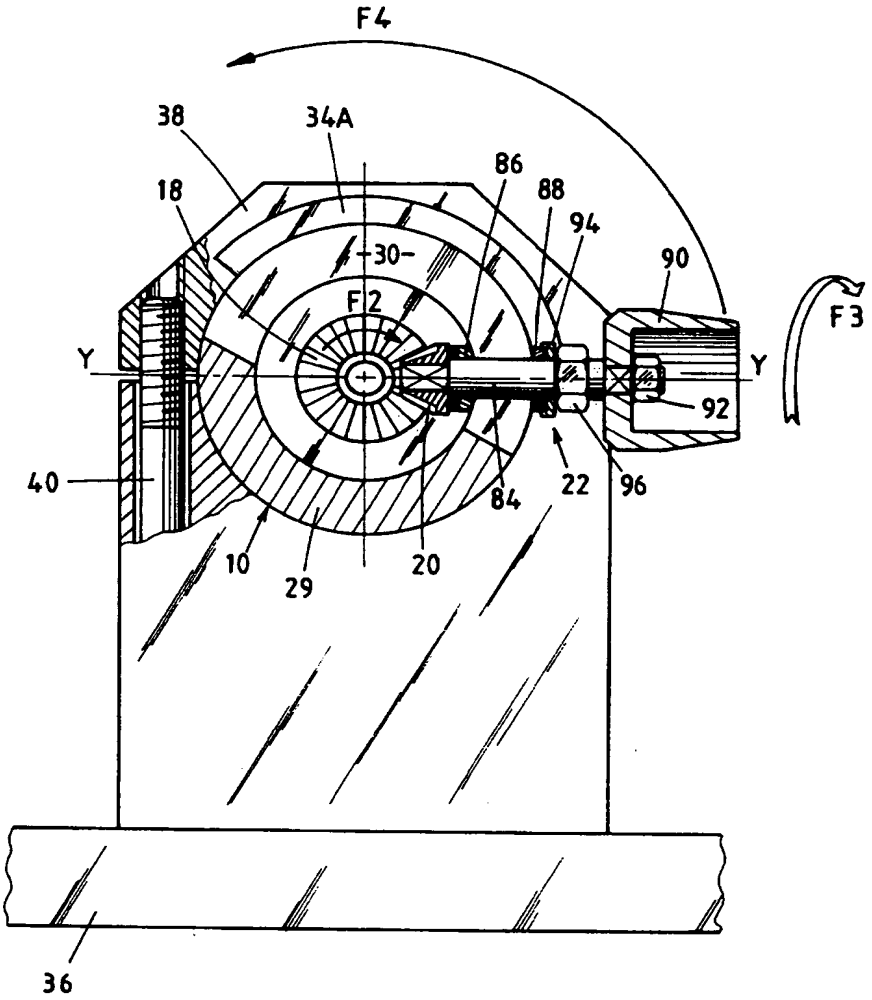

FIG.2

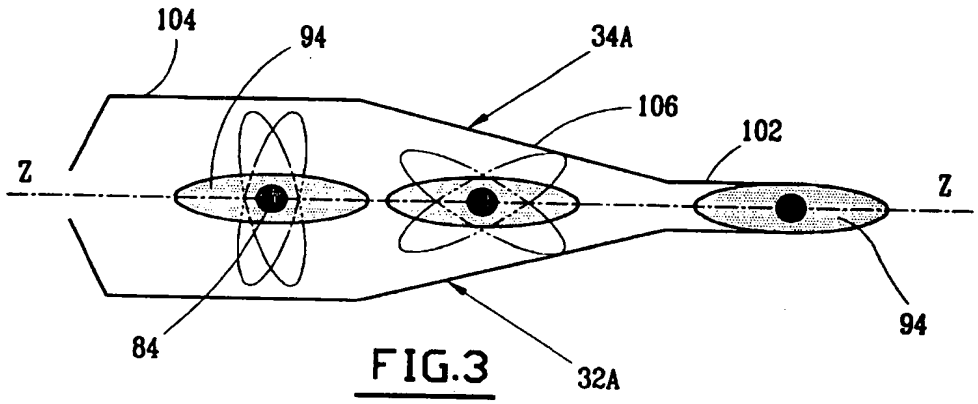

FIG.3

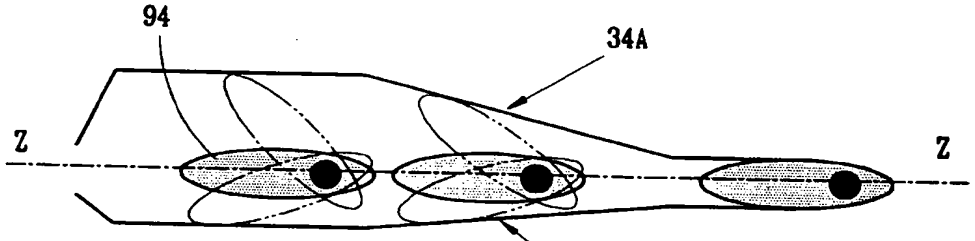

FIG.4

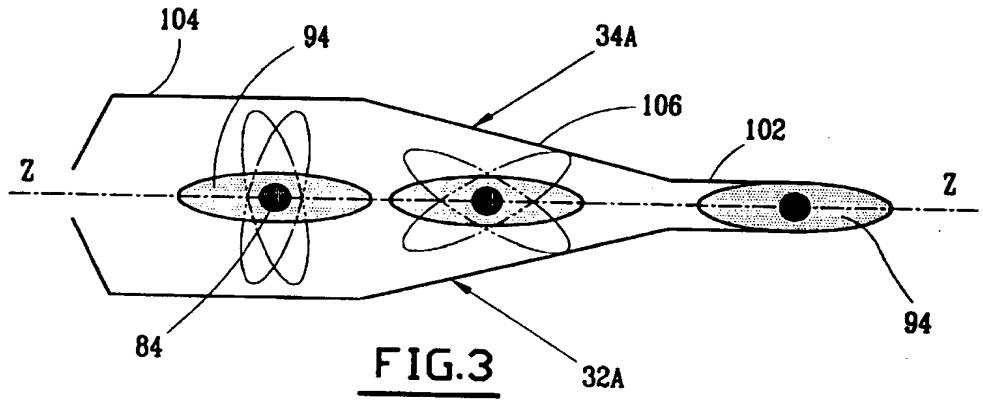

FIG.3

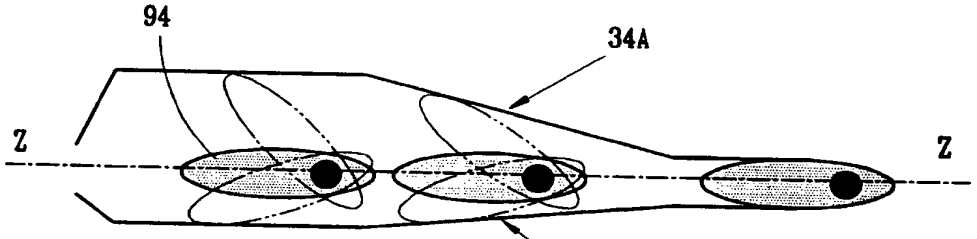

FIG.4

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(54) Apparatus and method for vascular hole closure

(57) An apparatus and method are disclosed for applying a surgical clip to an exterior wall of a blood vessel to at least partially close a hole formed therein. The apparatus includes a handle portion, an elongated body extending distally from the handle portion and dimensioned to extend through a hole in the wall of a blood vessel, and a collapsible locator associated with a distal end portion of the elongated body and mounted for movement between a collapsed position and an expanded deployed position. The locator is adapted to expand within an interior lumen of the blood vessel to maintain the distal end portion of the elongated body in a desired location with respect to the hole in blood vessel wall such that a surgical clip releasably supported adjacent the distal end portion of the elongated body can be applied to the exterior wall of the blood vessel to close the hole formed therein.

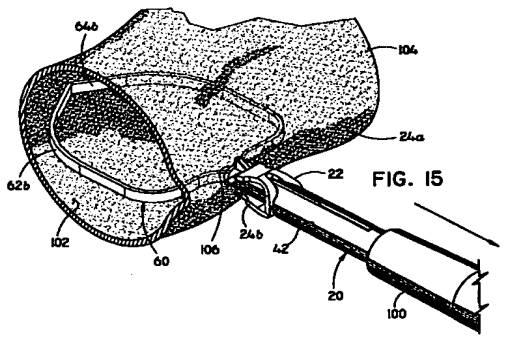


FIG. 15

EP 0 774 237 A2

Description

BACKGROUND

1. Technical Field

The present disclosure relates to an apparatus and method for closing a hole or puncture in a blood vessel, and more particularly, to an apparatus for applying a surgical clip to a blood vessel to close a hole formed therein during an intravascular catheterization procedure.

2. Background of Related Art

When performing a catheterisation procedure such as, for example, an angiography or angioplasty, a sharpened hollow needle is first percutaneously introduced into the vascular system. A guide wire is then inserted through the hollow needle and into the lumen of a selected blood vessel. Subsequently, the needle is removed and a dilator and/or introducer is fed into the vessel along the guide wire. The guide wire is then removed and a suitable catheter is fed through the lumen of the introducer and advanced through the vascular system until the working end thereof is positioned at the operating site. At the conclusion of the catheterization procedure, the catheter is withdrawn, and subsequently, the dilator and/or introducer is also removed from the wound.

At this point in the procedure, the vessel puncture must be sealed in order to stem the flow of blood therethrough. Because it is often common practice to administer a blood thinning agent to the patient prior to the catheterization procedures, stemming the blood flow can be troublesome. A common method of healing the wound is to maintain external pressure over the vessel until the puncture naturally seals. This method of puncture closure typically takes about thirty minutes, with the length of time usually being greater if the patient is hypertensive or anti-coagulated. When hand pressure is utilized, it can be uncomfortable for the patient and can use costly professional time on the part of the hospital staff. Other pressure application techniques, such as pressure bandages, sandbags or clamps, have been employed, but these devices also require the patient to remain motionless for an extended period of time and the patient must be closely monitored to ensure their effectiveness.

Other devices have been disclosed which plug or otherwise provide an obstruction in the area of the puncture. See, for example, U.S. Patent Nos. 4,852,568 and 4,890,612, wherein a collagen plug is disposed in the blood vessel opening. When the plug is exposed to body fluids, it swells to create a block for the wound in the vessel wall. A potential problem of plugs introduced into the vessel is that particles may break off and float downstream to the point where they may lodge in a smaller vessel, causing an infarct to occur. Collagen material also acts as a nidus for platelet aggregation and, therefore, can cause intraluminal deposition of hemostatic agent, thereby creating the possibility of a thrombosis at the puncture sight. Other plug-like devices are disclosed, for example, in U.S. Patent Nos. 5,342,393; 5,370,660; and 5,411,520.

Surgical clips and clip appliers are known and have been used in vascular surgery, particularly to join severed vessels. See, for example, U.S. Patent No. 4,929,240 (Kirsch, et al.). The clips disclosed in the '240 Patent provide an advantage over suturing by decreasing the likelihood of clotting and vascular damage, particularly in micro-vascular repair procedures. While vascular clips have been successfully used in surgery, the surgical procedures in which the clips are used typically allow the surgeon to view the area to be clipped. In catheter puncture repair procedures, however, the wound is generally not visible, making proper clip application, if attempted, difficult.

Therefore, there is a need for surgical techniques and apparatus suitable for closing punctures in blood vessels, particularly those created during catheterization procedures. This need requires a reliable hemostasis of the puncture in a quick and efficient manner. It would also be advantageous to close the puncture without disposing any foreign substances within the vessel, thereby preventing the likelihood of introducing foreign matter into the circulatory system. The technique also needs to be performed without directly viewing the punctured vessel.

SUMMARY

The subject application is directed to an apparatus and method for applying a surgical clip to an exterior wall of a blood vessel to at least partially close a hole formed therein during a catheterization procedure. The apparatus includes a handle portion, an elongated body extending distally from the handle portion and dimensioned to extend through a hole in the wall of a blood vessel, and a collapsible locator operatively associated with the elongated body and mounted for movement between a collapsed retracted position disposed within a distal end portion of the elongated body and an expanded deployed position extending from the distal end portion of the elongated body. The locator is preferably adapted and configured to expand within an interior lumen of the blood vessel in the deployed position to maintain the distal end portion of the elongated body in a desired location with respect to the hole in blood vessel wall. A surgical clip is releasably supported adjacent the distal end portion of the elongated body which is configured for application to the exterior wall of the blood vessel to at least partially close the hole formed therein when the locator is substantially in the deployed position.

Preferably, the surgical clip has a pair of opposed clip legs connected by a bail portion, and the bail portion has an aperture provided therein to accommodate

movement of the locator from the deployed position to the retracted position upon application of the clip to the exterior wall of the blood vessel. A control rod extends from the handle portion through the elongated body and is mounted for movement between a proximal position and a distal position to effectuate the movement of the collapsible locator between the retracted position and the deployed position, and a control knob is operatively mounted to a proximal end of the control rod to facilitate the longitudinal movement thereof. The control knob preferably includes means for releasably engaging the handle portion when the collapsible locator is disposed in the deployed position.

In a preferred embodiment of the subject apparatus, the elongated body includes an outer tubular member mounted for axial movement with respect to the handle portion between a proximal position and a distal position, and structure is provided adjacent a distal end of the elongated body for releasably supporting the surgical clip. A pair of diametrically opposed camming ramps are preferably formed adjacent a distal end of the elongated body, distal of the clip support structure, to cause the opposed legs of the surgical clip to move between a closed position and an open position in response to longitudinal movement of the outer tubular member from the distal position toward the proximal position.

An actuation handle is operatively associated with the handle portion of the surgical apparatus and is mounted for manipulation through an actuating stroke. Preferably, movement of the actuation handle through a first segment of the actuating stroke causes the outer tubular member to move from the proximal position to the distal position, and movement of the actuation handle through a second segment of the actuating stroke causes the actuation rod to move from the distal position to the proximal position. In addition, movement of the actuation handle through the second segment of the actuating stroke releases the control knob from an engaged position.

In a preferred embodiment of the surgical apparatus disclosed herein, distal and proximal actuating members are supported within the handle portion and are operatively connected to the actuation handle. Preferably, a first control link connects the distal actuating member to the actuation handle and second control link connects the proximal actuating member to the actuation handle. The distal actuating member is also connected to a proximal end of the outer tubular member, and the proximal actuating member is also connected to a release tube which is dimensioned to interact with the control knob upon movement of the actuation handle through the second segment of the actuating stroke.

The method disclosed herein includes the steps of taking an elongated body having a surgical clip supported adjacent a distal end portion thereof, extending the elongated body through the hole in the blood vessel such that at least a distal end portion thereof projects into an interior lumen of the blood vessel, and deploying a locator from the distal end portion of the elongated body into the interior lumen of the blood vessel to maintain the elongated body in a desired position with respect to the hole in the wall of the blood vessel. The method further includes the steps of applying the surgical clip to the exterior wall of the blood vessel to at least partially close the hole therein, and retracting the locator from the interior lumen of the blood vessel.

In a preferred embodiment of the method, the step of applying the surgical clip includes the step advancing the surgical clip in a distal direction from a proximal support position on the elongated body, and the step of moving the surgical clip between open and closed positions. The step of deploying the locator includes the step of moving the locator from a collapsed position within the distal end position of the elongated body to an expanded position extending from the distal end portion of the body. Preferably, the step of withdrawing the locator is concomitant with the step of applying the surgical clip to the exterior wall of the blood vessel.

Further features of the surgical apparatus and method of the subject application will become more readily apparent to those skilled in the art from the following detailed description of the apparatus and method taken in conjunction with the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments of the surgical apparatus and method of the subject application will be described hereinbelow with reference to the drawings wherein:

Fig. 1 is a perspective view of a surgical apparatus constructed in accordance with a preferred embodiment of the subject invention in a pre-operative condition;

Fig. 2 is an enlarged perspective view of the distal end portion of the surgical apparatus of Fig. 1 illustrating the surgical clip releasably supported thereon;

Fig. 3 is an exploded perspective view of the elongated body of the surgical apparatus of Fig. 1 with the components thereof separated for ease of illustration;

Fig. 4 is an enlarged perspective view of the distal end portion of the elongated body of Fig. 3 illustrating the surgical clip and clip support structure associated therewith;

Fig. 5 is an enlarged perspective view of the distal end portion of the clip advancement tube of the elongated body illustrated in Fig. 3;

Fig. 6 is a perspective view of the handle portion of the surgical apparatus of Fig. 1 with the left housing section removed to illustrate the internal compo-

nents housed therein;

Fig. 7 is an exploded perspective view of the handle portion shown in Fig. 6 with the components thereof separated for ease of illustration;

Fig. 8 is an exploded perspective view of the locator and the distal end portion of the control rod to which the locator is mounted;

Fig. 9 is an enlarged perspective view of the coupling area of the locator illustrated in Fig. 8;

Fig. 10 is a perspective view of the locator in an expanded condition mounted to the distal end of the control rod;

Fig. 11 is a perspective view of a cannula extending through a hole in the wall of a blood vessel with the elongated body of the surgical apparatus of Fig. 1 extended therethrough;

Fig. 12 is an enlarged perspective view of the locator extended from the distal end portion of the surgical apparatus of Fig. 1 and collapsed within the cannula;

Fig. 13 is a side elevational view in cross-section of the handle portion of the surgical apparatus of Fig. 1 illustrating the relative orientation of the internal components associated therewith in a pre-operative condition;

Fig. 14 is a side-elevational view in cross-section of the handle portion of the surgical apparatus of Fig. 1 illustrating the relative orientation of the internal components associated therewith in a condition corresponding to the locator being disposed in a deployed position;

Fig. 15 is a perspective view of a distal end portion of the elongated body of the surgical apparatus of Fig. 1 illustrating the locator disposed in a deployed position within the interior lumen of a blood vessel;

Fig. 16 is a side elevational view in cross-section of the handle portion of the surgical apparatus of Fig. 1 illustrating the relative orientation of the components associated therewith in positions corresponding to the clip advancement tube being advanced toward a distal position;

Fig. 17 is a perspective view of the distal end portion of the elongated body of the surgical apparatus of Fig. 1 illustrating the clip advancement tube advanced distally to cause the surgical clip to move to an open position;

Fig. 18 is a side-elevational view corresponding to Fig. 17 and illustrating the surgical clip in an open position;

Fig. 19 is a perspective view of the distal end portion of the elongated body of the surgical apparatus of Fig. 1 illustrating the clip advancement tube advanced to a distal-most position to cause the surgical clip to move to a closed position;

Fig. 20 is a side elevational view corresponding to Fig. 19 and illustrating the surgical clip in a closed position;

Fig. 21 is a side elevational view in cross-section of the handle portion of the surgical apparatus of Fig. 1 illustrating the relative orientation of the components associated therewith in positions corresponding to the locator being withdrawn to a retracted position; and

Fig. 22 is a side elevational view of the surgical clip applied to the exterior wall of the blood vessel to close the hole formed therein.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

In the drawings and in the description which follows, the term "proximal", as is traditional, will refer to the end of the apparatus which is closest to the operator, while the term "distal" will refer to the end of the apparatus which is furthest from the operator.

Referring now to the drawings wherein like reference numerals identify similar structural elements disclosed herein, there is illustrated in Fig. 1 a surgical apparatus constructed in accordance with a preferred embodiment of the subject application and designated generally be reference numeral 10. Surgical apparatus 10 is adapted and configured to apply a surgical clip to the exterior wall of a blood vessel to at least partially close a hole formed therein during a catheterization procedure, such as, for example, an angioplasty or angiography procedure.

Referring to Fig. 1, surgical apparatus 10 includes a handle assembly 12 consisting of right and left housing sections 12a and 12b which together define an elongated barrel portion 14, a stationary handle 16 depending from barrel portion 14, and a pivoting actuation handle or trigger 18 mounted for movement with respect to stationary handle 16. An elongated body 20 extends distally from the barrel portion 14 of handle assembly 12, and a surgical clip 22 is releasably supported on a distal end portion of elongated body 20, as illustrated in Fig. 2. As best seen in Fig. 4, surgical clip 22 includes a pair of opposed clip legs 24a and 24b connected to one another by a bail portion 26. Each clip leg is provided with a pair of tissue engagement projections 25 for securely engaging the exterior wall of the blood vessel to which it is applied (see Fig. 22). Clip legs 24a and 24b

are normally biased into a closed position resulting from the overall configuration of surgical clip 22 and the material from which the clip is constructed. The material of construction may be selected from a group consisting of bio-compatible materials, including, for example, stainless steel, titanium, and tantalum. Other materials of construction such as bio-absorbable polymers are also envisioned.

Referring to Fig. 3, the elongated body 20 of surgical apparatus 10 includes a main support shaft 30 having an elongated bore 30a extending therethrough. Support shaft 30 extends through the barrel portion 14 of handle assembly 10 and is mounted adjacent a proximal end thereof in a conventional manner. A clip support fixture 34 is mounted in axial bore 30a adjacent the distal end of support shaft 30. As best seen in Fig. 4, support fixture 34 is configured to releasably support surgical clip 22 and includes a pair of diametrically opposed rails 36a and 36b dimensioned to interact with a crescent shaped aperture 38 defined in the bail portion 26 of surgical clip 22. Rails 36a and 36b terminate in distally extending camming ramps 40a and 40b, respectively, which effectuate movement of clip legs 24a and 24b between closed and open positions as surgical clip 22 is advanced in a distal direction during a hole closing procedure.

Advancement of surgical clip 22 in a distal direction relative to camming ramps 40a and 40b is accomplished through the axial translation of an elongated pusher tube 42. Pusher tube 42 is mounted coaxial with support shaft 30 and is configured to translate with respect thereto in response to manipulation of actuation handle 18 to drive surgical clip 22 distally. As best seen in Fig. 5, spaced apart arcuate engagement fingers 44a and 44b project distally from pusher tube 42 to engage the crescent spaced aperture 38 defined in the bail portion 26 of surgical clip 22. Diametrically opposed elongate slots 46a and 46b are formed in the distal portion of pusher tube 42 to accommodate rails 36a and 36b during the distal translation of the pusher tube with respect to support shaft 30.

Referring now to Figs. 6 and 7, a set pin 45 fixedly connects the proximal end of pusher tube 42 to a distal actuation block 48 which is housed within the barrel portion 14 of handle assembly 12. Actuation block 48 includes opposed lateral guide ribs 50a and 50b which translate within opposed guide slots formed in the interior surfaces of right and left housing sections 12a and 12b, i.e., guide slot 53. A coupling link 54 connects distal actuation block 48 to actuation handle 18 such that manipulation of actuation handle 18 causes actuation block 48 to translate distally, urging pusher tube 42 in a distal direction. Coupling pins 54a and 54b pivotally connect coupling link 54 to actuation block 48 and actuation handle 18.

Referring now to Figs. 8-10, surgical apparatus 10 also includes a locator 60 in the form of a collapsible loop or ring adapted and configured to maintain the distal end portion of elongated body 20 in a desired position with respect to the hole in the wall of a blood vessel during a hole closing procedure. Locator 60 includes a pair of locator arms 62 and 64 which are constructed from a resilient material that preferably displays shape memory characteristics, such as, for example, a material or alloy consisting of a composition of nickel and titanium. Locator arms 62 and 64 include elongate proximal extension portions 62a and 64a, respectively, and arcuate expansion portions 62b and 64b, respectively. As best seen in Fig. 9, the terminal end of arcuate expansion portion 62b includes an engagement notch 63 for receiving and retaining a complementary engagement finger 65 formed at the terminal end of arcuate expansion portion 64b. When engaged and situated in a relaxed unstressed condition, resilient expansion portions 62b and 64b form an endless loop-like structure. As best seen in Fig. 8, when assembled, the proximal ends of extension portions 62a and 64a are approximated and secured to a coupling flange 66 which is provided at the distal end of an elongated control rod 68 which facilitates movement of locator 60 with respect to support tube 30 during a hole closing procedure.

Referring again to Figs. 6 and 7, the elongated control rod 68 extends through the axial bore 30a of support tube 30, into the barrel portion 14 of handle assembly 12, through the axial bores 48a and 70a of distal and proximal actuation blocks 48 and 70, out of the proximal end of barrel portion 14, and into the axial bore 75a of a cylindrical control knob 75 operatively associated with handle assembly 12. The proximal end of control rod 68 is fixedly maintained within axial bore 75a of control knob 75 by a fastener 77 (see Fig. 13). Control knob 75 facilitates the longitudinal translation of control rod 68 between proximal and distal positions, and hence the movement of locator 60 from a collapsed (stressed) position disposed within the axial bore 34a of support fixture 34 to a deployed (unstressed) position extending from the distal end of support fixture 34. Control knob 75 includes a pair of engagement tabs 74a and 74b for releasably engaging a pair of complementary retention notches formed on the exterior of housing sections 12a and 12b, i.e., retention notch 76, when locator 60 is disposed in a deployed position.

With continuing reference to Figs. 6 and 7, an elongated release tube 78 extends proximally from the proximal actuation block 70 to interact with, and effect the disengagement of control knob 75 upon manipulation of actuation handle 18. More particularly, proximal actuation block 70, which includes guide ribs 72a and 72b that translate within opposed guide slots formed in housing sections 12a and 12b, i.e., guide slot 73, is connected to actuation handle 18 by a coupling link 82. Coupling pins 82a and 82b pivotably connect coupling link 82 to actuation block 70 and actuation handle 18. Thus, manipulation of actuation handle 18 causes actuation block 70 to translate in a proximal direction, whereupon release tube 78 enters the axial bore 75a of control knob 75 and urges the control knob proximally to disengage tabs 74a and 74b. As discussed in further

detail hereinbelow, the distal and proximal actuation blocks 48 and 70 are connected to actuation handle 18 in such a manner so that control knob 75 will not be released until pusher tube 42 has been advanced to its distal-most position.

Referring now to Fig. 11, in use, the elongated body 20 of surgical apparatus 10 is introduced into the interior lumen 102 of blood vessel 104 through a conventional cannula 100 which had previously been extended through the hole 106 formed in the wall of blood vessel 104 during the catheterization procedure. Thereupon, locator 60 is moved distally through the translation of control knob 75 from its proximal-most position illustrated in Fig. 13 to its distal-most position illustrated in Fig. 14. Moreover, locator 60 is advanced from its proximal-most position disposed within the axial bore 34a of clip support fixture 34 to its distal-most position extending from the distal end of clip support fixture 34. At such a time, the arcuate expansion portions 62b and 64b of locator arms 62 and 64 remain in a collapsed (stressed) condition restrained within the interior lumen of cannula 100, as best seen in Fig. 12. When control knob 75 is in its proximal-most position shown in Fig. 14, engagement tabs 74a and 74b are releasably engaged to the proximal end of barrel portion 14, thereby securing the longitudinal orientation of control rod 68 and locator 60.

Referring now to Fig. 15, after locator 60 is moved into its distal-most position, cannula 100 is withdrawn in a proximal direction with respect to elongated body 20 to a retracted position. Consequently, the arcuate expansion portions 62b and 64b of locator arms 62 and 64 move into their deployed (unstressed) positions, forming the loop-like structure which maintains the distal end portion of elongated body 20 in a desired position with respect to the hole 106 in the wall of blood vessel 104. In this deployed position, the geometric plane defined by locator 60 is oriented parallel to the elongation of blood vessel 104. Accordingly, the opposed clip legs 24a and 24b of surgical clip 22 extend in a direction which is perpendicular to the elongation of blood vessel 104.

Once locator 60 is deployed, the clip application portion of the vascular hole closure procedure may commence. To apply surgical clip 22 to the exterior wall of blood vessel 104 to at least partially close the hole 106 formed therein, actuation handle 18 is initially moved through the first segment of an actuation stroke, with guide pin 90 serving as the pivot point for actuation handle 18. During this time, actuation handle 18 causes the distal actuation block 48 to translate from its proximal-most position illustrated in Fig. 14 to its distal-most position illustrated in Fig. 16 through a distance "x_d" within the barrel portion 14 of handle assembly 12. As a result, pusher tube 42 is driven distally, urging surgical clip 22 in a distal direction.

Initially, during the distal advancement of surgical clip 22, the opposed clip legs 24a and 24b of surgical clip 22 are moved to an open position as the clip translates with respect to camming ramps 40a and 40b, as illustrated in Figs 17 and 18. Subsequently, as actuation block 48 approaches its distal-most position within barrel portion 14, pusher tube 42 advances surgical clip 22 passed camming ramps 40a and 40b so that clip legs 24a and 24b return to a closed portion, as illustrated in Figs. 19 and 20. More specifically, when camming ramps 40a and 40b meet the crescent shaped aperture 38 in the bail portion 26 of surgical 22, clip legs 24a and 24b return to their normally biased closed position.

Referring back to Fig. 14, prior to the manipulation of actuation handle 18 through the first segment of its actuating stroke, the proximal end of release tube 78 is disposed slightly distal of the axial bore 75a of control knob 75. As shown in Fig. 16, however, during the manipulation of actuation handle 18 through the first segment of its actuating stroke, the proximal actuation block 70 and release tube 78 translate in a proximal direction through a distance "x_p" which is substantially less than the distance "x_d" through which the distal actuation block 48 travels during the same period of time. Consequently, during the first segment of the actuating stroke of actuation handle 18, the proximal end of release tube 78 translates only a short distance within the axial bore 75a of control knob 75, remaining free from contact with the proximal wall of axial bore 75a, and having no effect of the longitudinal position of control knob 75.

However, as illustrated in Fig. 21, once the distal actuation block 48 reaches its distal-most position, the pivot point of actuation handle 18 transfers from guide pin 90 to coupling pin 54a. As a result, the remaining portion of the actuating stroke of actuation handle 18 is guided by the interaction of guide pin 90 and the arcuate guide slot 92 formed in actuation handle 18. Consequently, further manipulation of actuation handle 18 toward stationary handle 16 urges proximal actuation block 70 in a proximal direction, driving release tube 78 proximally. As a consequence, control knob 75 is urged proximally, causing the release of engagement tabs 74a and 74b from the complementary notches formed at the proximal end of barrel portion 14, and effectuating the proximal withdrawal of control rod 68 relative to support tube 30. Accordingly, the arcuate expansion portions 62b and 64b of locator 60 are withdrawn into the axial bore 34a of support fixture 34, through the crescent shaped aperture 38 formed in the bail portion 26 of surgical clip 22.

Following the withdrawal of locator 60 into the axial bore 34a of support fixture 34, the distal end portion of the elongated body 20 of surgical apparatus 10 may be withdrawn from the surgical site. As best seen in Fig. 22, at the conclusion of the procedure, the opposed legs 24a and 24b of surgical clip 22 are securely engaged to the exterior wall of blood vessel 104 such that the hole once formed therein is closed, thereby preventing blood from flowing therethrough.

Claims

1. An apparatus for applying a surgical clip to an exterior wall of a blood vessel to at least partially close a hole formed therein comprising:

   a) a handle portion;

   b) an elongated body extending distally from the handle portion and dimensioned to extend through a hole in the wall of a blood vessel;

   c) a collapsible locator operatively associated with the elongated body and mounted for movement between a collapsed retracted position disposed within a distal end portion of the elongated body and an expanded deployed position extending from the distal end portion of the elongated body, the locator ring being adapted and configured to expand within an interior lumen of the blood vessel in the deployed position to maintain the distal end portion of the elongated body in a desired location with respect to the hole in blood vessel wall; and

   d) a surgical clip releasably supported adjacent the distal end portion of the elongated body and configured for application to the exterior wall of the blood vessel to at least partially close the hole formed therein when the locator is substantially in the deployed position.

2. An apparatus as recited in Claim 1, wherein the locator has a generally loop-like configuration in the deployed position.

3. An apparatus as recited in Claim 1 or 2, wherein at least a portion of the locator is formed from a material having shape memory characteristics.

4. An apparatus as recited in Claim 1, 2 or 3, wherein the surgical clip has a pair of opposed clip legs connected by a bail portion, and the bail portion has an aperture provided therein to accommodate movement of the locator from the deployed position to the retracted position upon application of the clip to the exterior wall of the blood vessel.

5. An apparatus as recited in Claim 4, wherein a control rod extends from the handle portion through the elongated body and is mounted for movement between a proximal position and a distal position to effectuate the movement of the collapsible locator between the retracted position and the deployed position.

6. An apparatus as recited in Claim 5, wherein a control knob is operatively mounted to a proximal end of the control rod to facilitate the longitudinal movement thereof.

7. An apparatus as recited in Claim 6, wherein the control knob includes a pair of opposed locking tabs configured to releasably engage complementary reception structures provided on a proximal end portion of the handle portion when the collapsible locator is disposed in the deployed position.

8. An apparatus as recited in any one of the preceding claims, wherein the elongated body includes an outer tubular member mounted for axial movement with respect to the handle portion between a proximal position and a distal position.

9. An apparatus as recited in any one of the preceding claims, wherein support structure is provided adjacent a distal end of the elongated body for releasably supporting the surgical clip.

10. An apparatus a recited in Claim 9, wherein a pair of diametrically opposed camming ramps are formed adjacent a distal end of the elongated body distal of the clip support structure, the camming ramps causing the opposed arms of the surgical clip to move between a closed position and an open position in response to longitudinal movement of the outer tubular member from the distal position toward the proximal position.

11. An apparatus as recited in any one of the preceding claims, wherein an actuation handle is operatively associated with the handle portion and is mounted for manipulation through an actuating stroke.

12. An apparatus as recited in Claim 11, wherein movement of the actuation handle through a first segment of the actuating stroke causes the outer tubular member to move from the proximal position to the distal position, and movement of the actuation handle through a second segment of the actuating stroke causes the control rod to move from the distal position to the proximal position.

13. An apparatus as recited in Claim 12, wherein movement of the actuation handle through the second segment of the actuating stroke releases the control knob from an engaged position.

14. An apparatus as recited in Claim 12 or 13, wherein distal and proximal actuating members are supported with the handle portion and are operatively connected to the actuation handle, the distal actuating member connected to a proximal end of the outer tubular member and the proximal actuating member connected to a release tube which is dimensioned to interact with the control knob upon movement of the actuation handle through the sec-

ond segment of the actuating stroke.

15. An apparatus as recited in Claim 14, wherein a first control link connects the distal actuating member to the actuation handle and second control link connects the proximal actuating member to the actuation handle.

16. An apparatus for applying a surgical clip to an exterior wall of a blood vessel to at least partially close a hole formed therein comprising:

a) a handle portion;

b) an elongated body extending distally from the handle portion and dimensioned to extend through a hole in the wall of a blood vessel; and

c) a collapsible locator operatively associated with a distal end portion of the elongated body and mounted for movement between a collapsed retracted position and an expanded deployed position, the locator being adapted and configured to expand within an interior lumen of the blood vessel to maintain the distal end portion of the elongated body in a desired location with respect to the hole in the blood vessel wall, such that a surgical clip releasably supported adjacent the distal end portion of the elongated body can be applied to the exterior wall of the blood vessel to at least partially close the hole formed therein when the locator is substantially in the deployed position.

17. An apparatus for applying a surgical clip to an exterior wall of a blood vessel to at least partially close a hole formed therein comprising:

a) a handle portion including an actuation handle mounted for movement through an actuating stroke;

b) an elongated body extending distally from the handle portion and dimensioned to extend through a hole in the wall of a blood vessel;

c) a collapsible locator loop operatively associated with the elongated body and mounted for movement between a collapsed retracted position disposed within a distal end portion of the elongated body and an expanded deployed position extending from the distal end portion of the elongated body, the locator loop being adapted and configured to expand within an interior lumen of the blood vessel in the deployed position to maintain the distal end portion of the elongated body in a desired location with respect to the hole in the blood vessel wall;

d) a surgical clip releasably supported adjacent the distal end of the elongated body and configured for application to the exterior wall of the blood vessel to at least partially close the hole formed therein, the surgical clip having a pair of opposed clip legs connected by a bail portion, the bail portion having an aperture provided therein to accommodate movement of the locator loop between the deployed position and the retracted position; and

e) an actuation assembly housed within the handle portion and operatively connected to the actuation handle such that movement of the actuation handle through a first segment of the actuating stroke effectuates longitudinal movement of the surgical clip toward the exterior wall of the blood vessel and movement of the actuation handle through a second segment of the actuating stroke effectuates movement of the collapsible locator loop from the deployed position to the retracted position.

18. An apparatus as recited in Claim 17, wherein a control rod extends from the handle portion through the elongated body portion and is mounted for movement between a proximal position and a distal position to effectuate the movement of the collapsible locator loop between the retracted position and the deployed position.

19. An apparatus as recited in Claim 18, wherein a control knob is operatively mounted to a proximal end of the control rod to facilitate the longitudinal movement thereof and includes means for releasably engaging the handle portion when the collapsible locator loop is disposed in the deployed position.

20. An apparatus as recited in Claim 19, wherein the elongated body portion includes an outer tubular member mounted for axial movement with respect to the handle portion between a proximal position and a distal position.

21. An apparatus a recited in Claim 20, wherein a pair of diametrically opposed camming ramps are formed adjacent a distal end of the elongated body, distal of the clip support position, the camming ramps causing the opposed legs of the surgical clip to move between a closed position and an open position in response to longitudinal movement of the outer tubular member from the distal position toward the proximal position.

22. An apparatus as recited in Claim 21, wherein movement of the actuation handle through the first segment of the actuating stroke causes the outer tubular member to move from the proximal position to the distal position, and movement of the actua-

tion handle through the second segment of the actuating stroke causes the actuation rod to move from the distal position to the proximal position.

23. An apparatus as recited in Claim 22, wherein movement of the actuation handle through the second segment of the actuating stroke releases the control knob from an engaged position.

24. An apparatus as recited in Claim 23, wherein the actuating assembly includes a distal actuating member connected to a proximal end of the outer tubular member and a proximal actuating member connected to a release tube which is dimensioned to interact with the actuator upon movement of the actuation handle through the second segment of the actuating stroke.

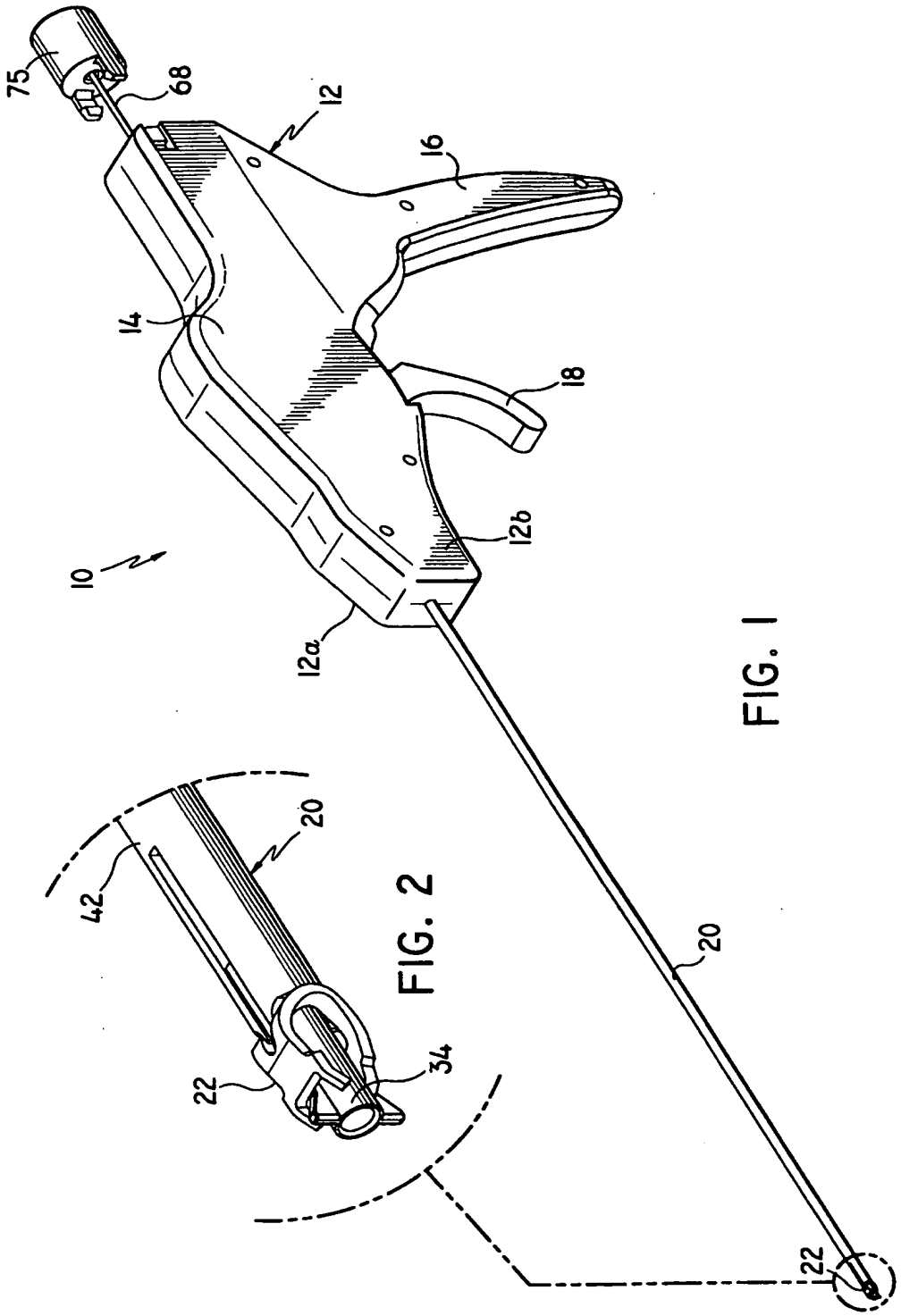


FIG. 1

FIG. 2

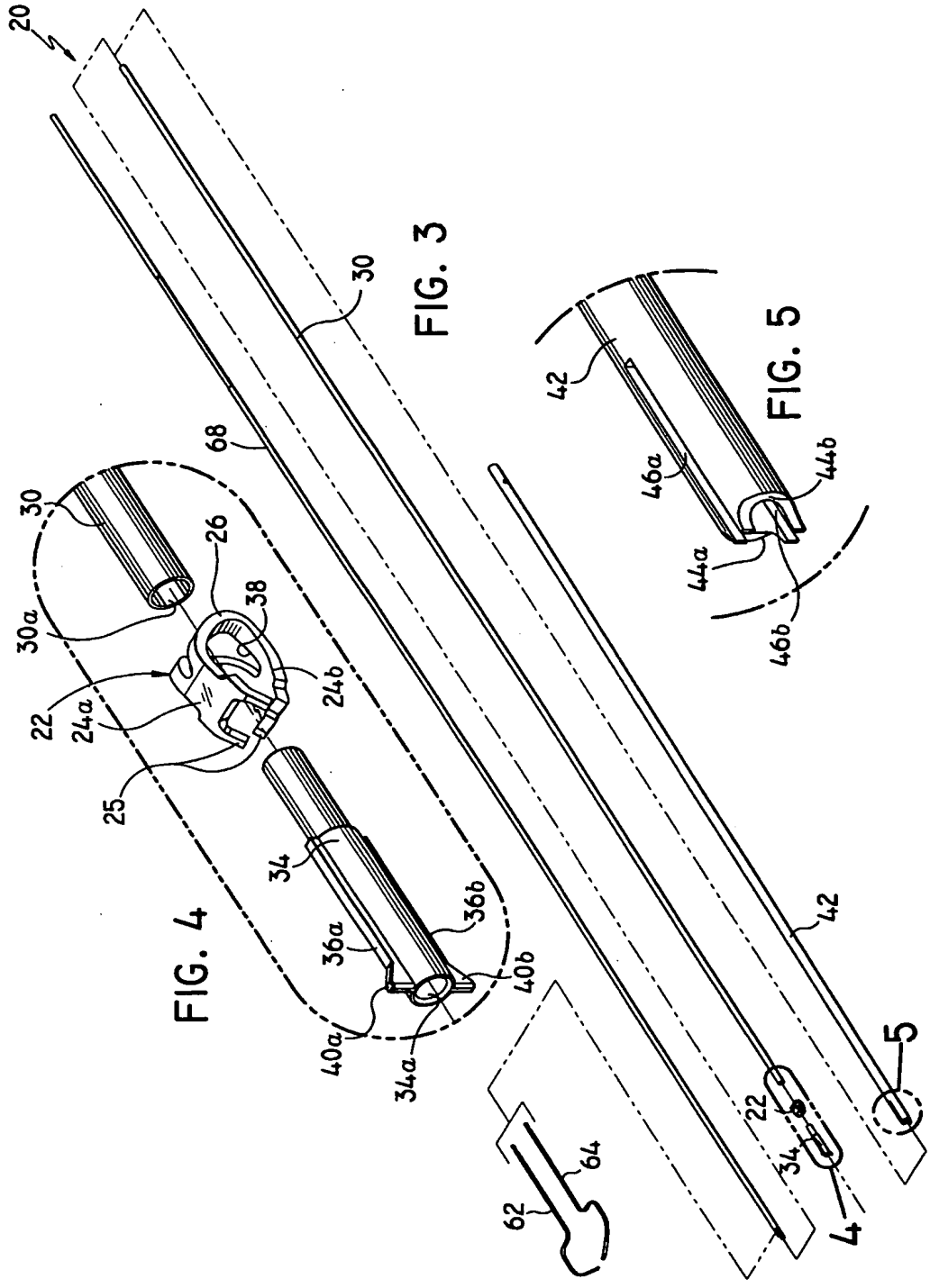


FIG. 3

FIG. 4

FIG. 5

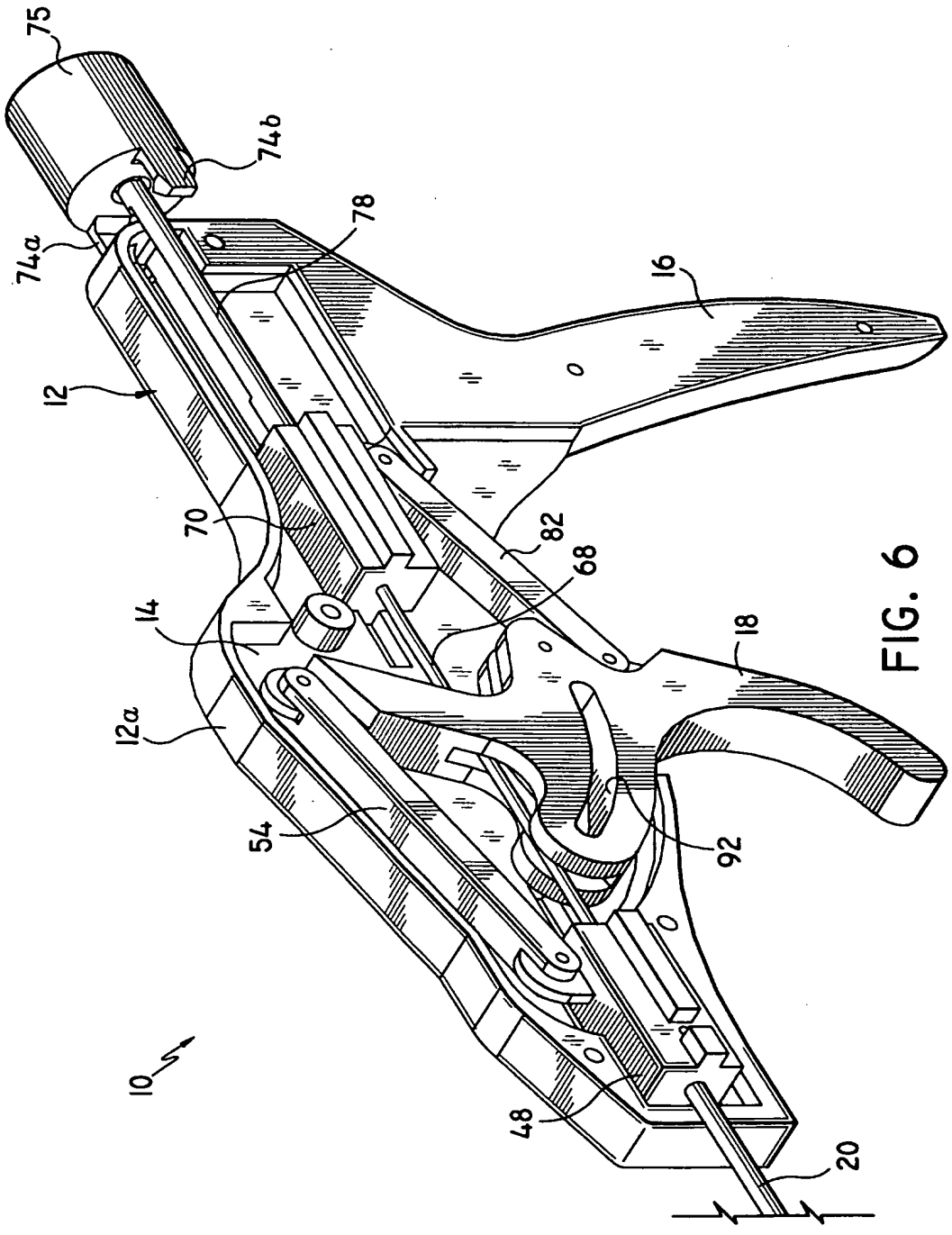


FIG. 6

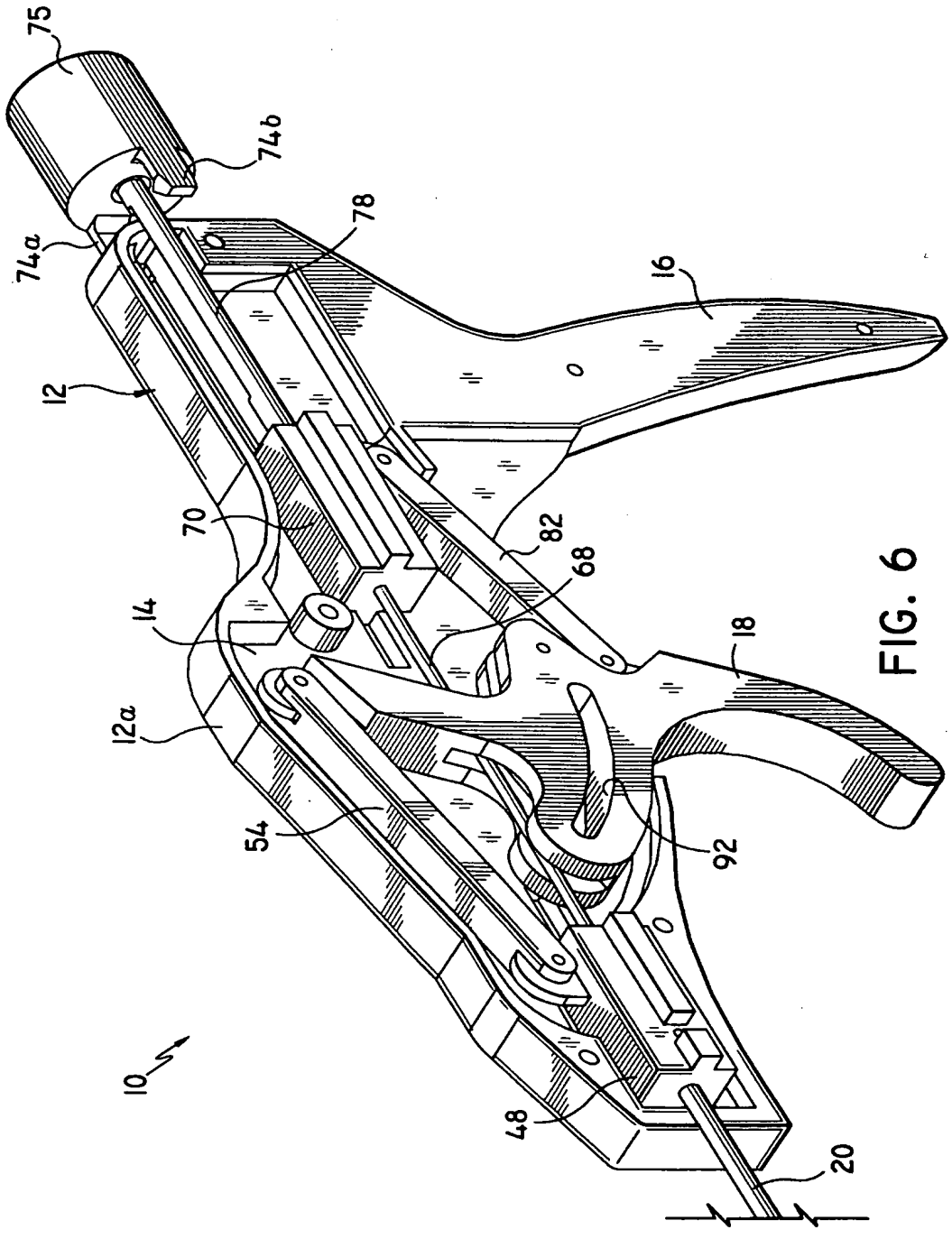
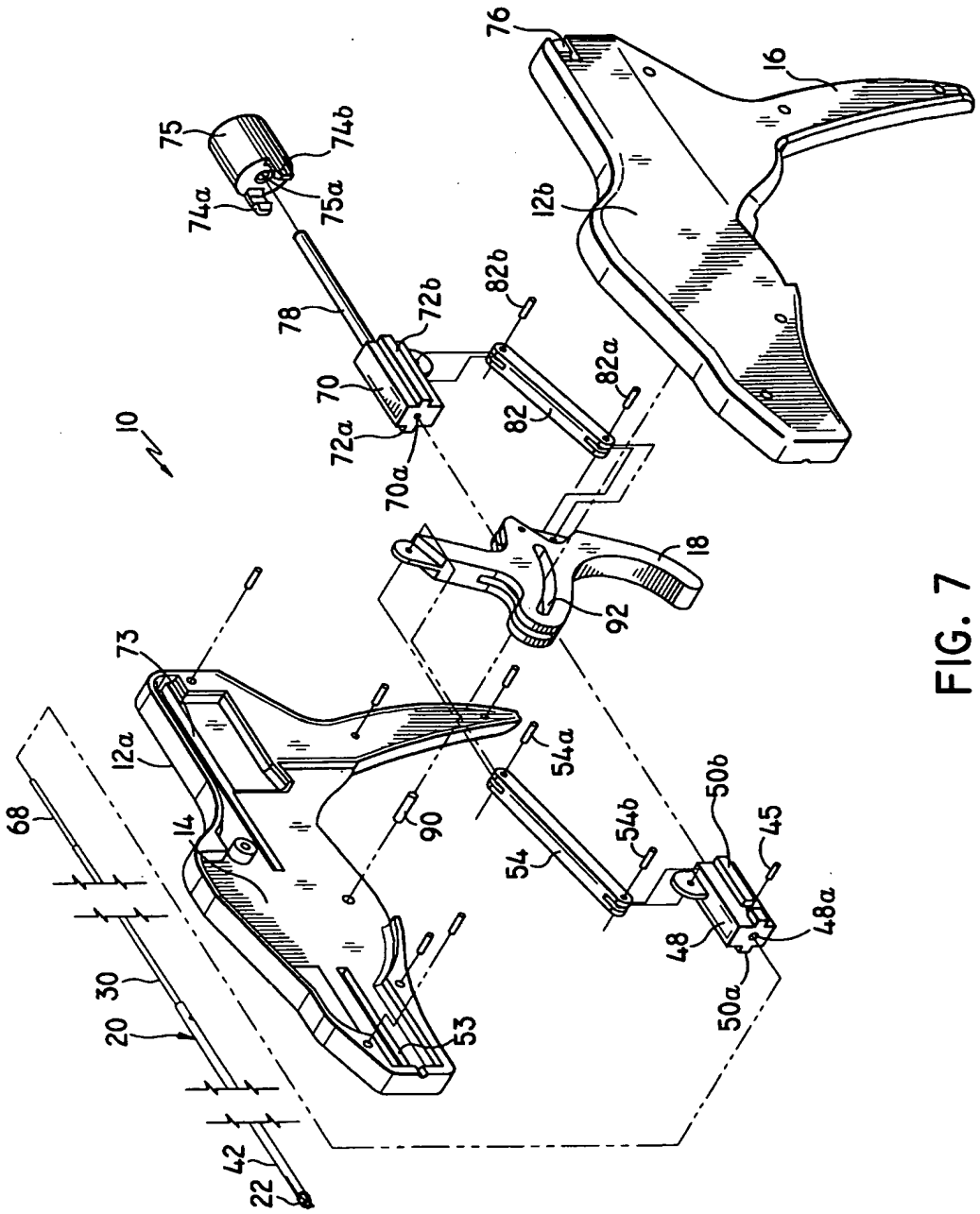


FIG. 6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16
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74b
74a
75a
12b
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72b
82b
70
82a
72a
82
70a
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92
73
12a
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30
50a
20
53
42
22

FIG. 7

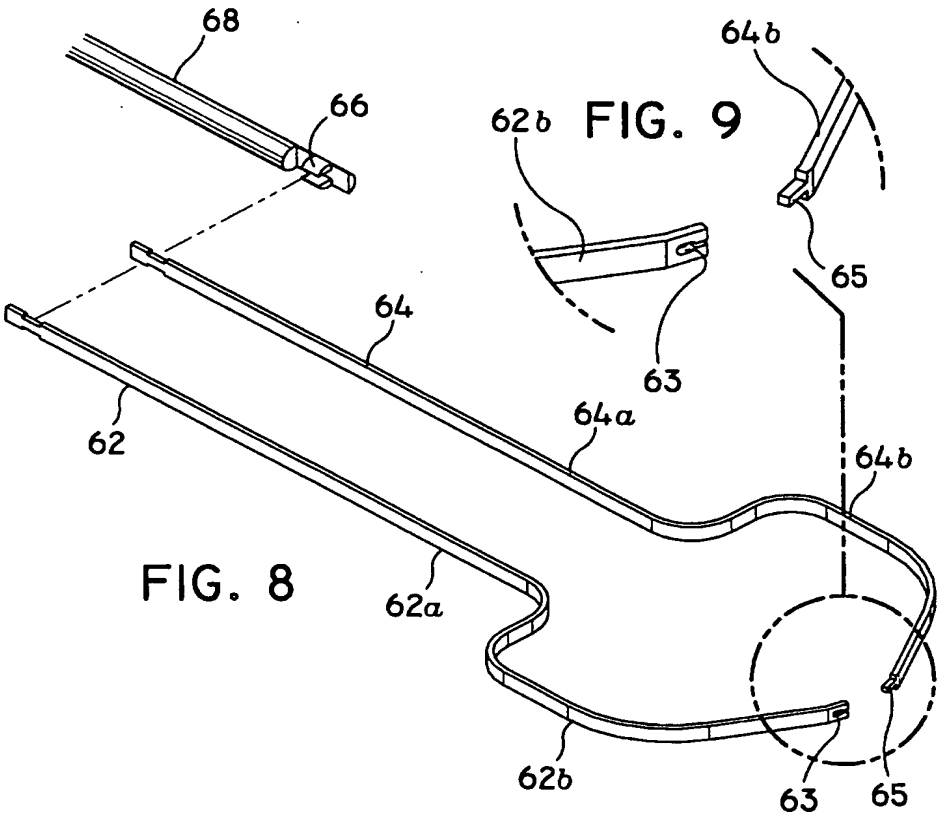

FIG. 8

FIG. 9

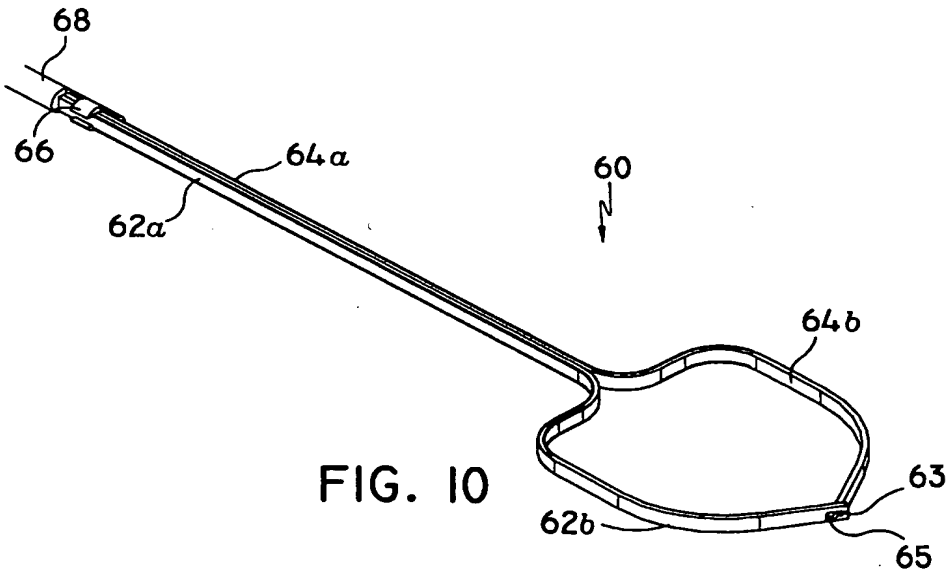

FIG. 10

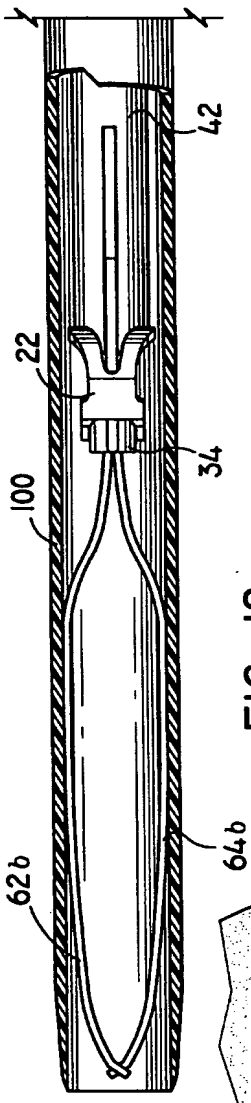

FIG. 12

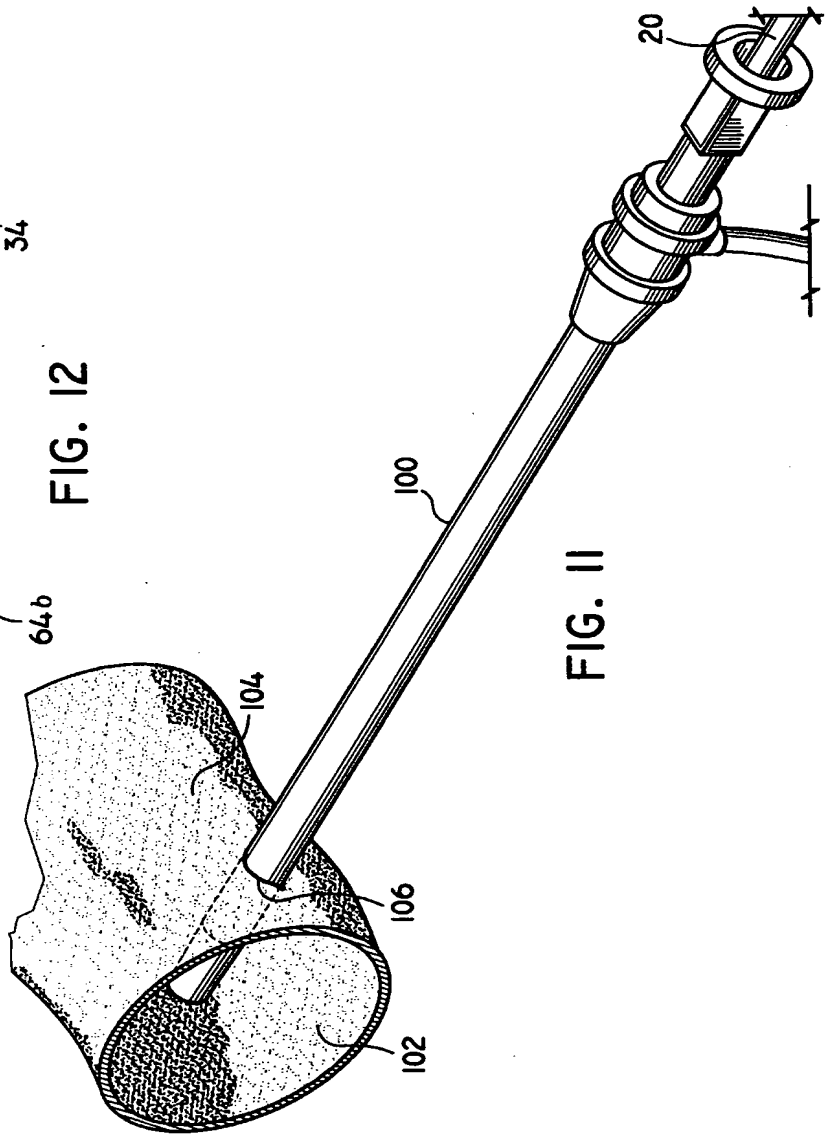

FIG. 11

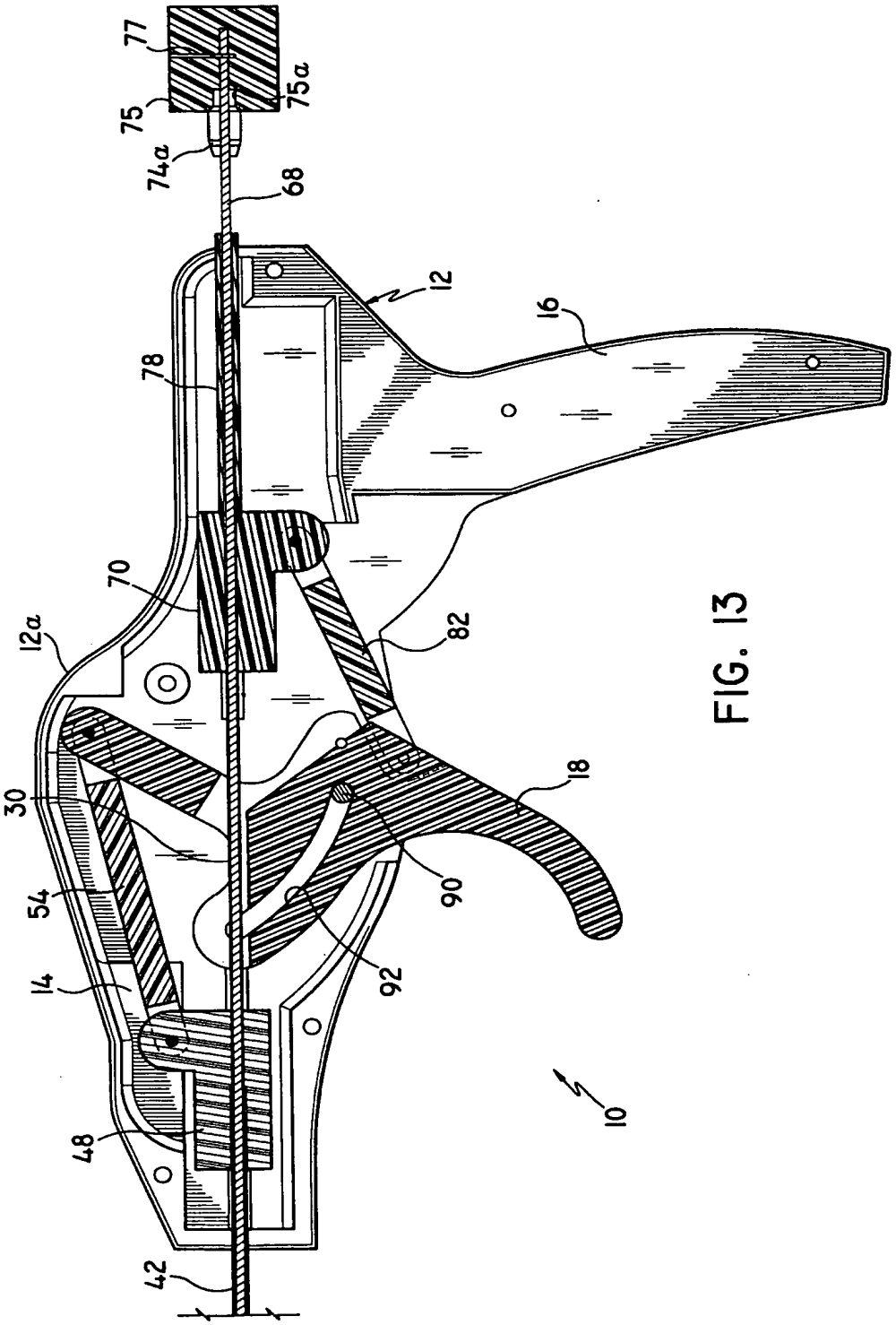

FIG. 13

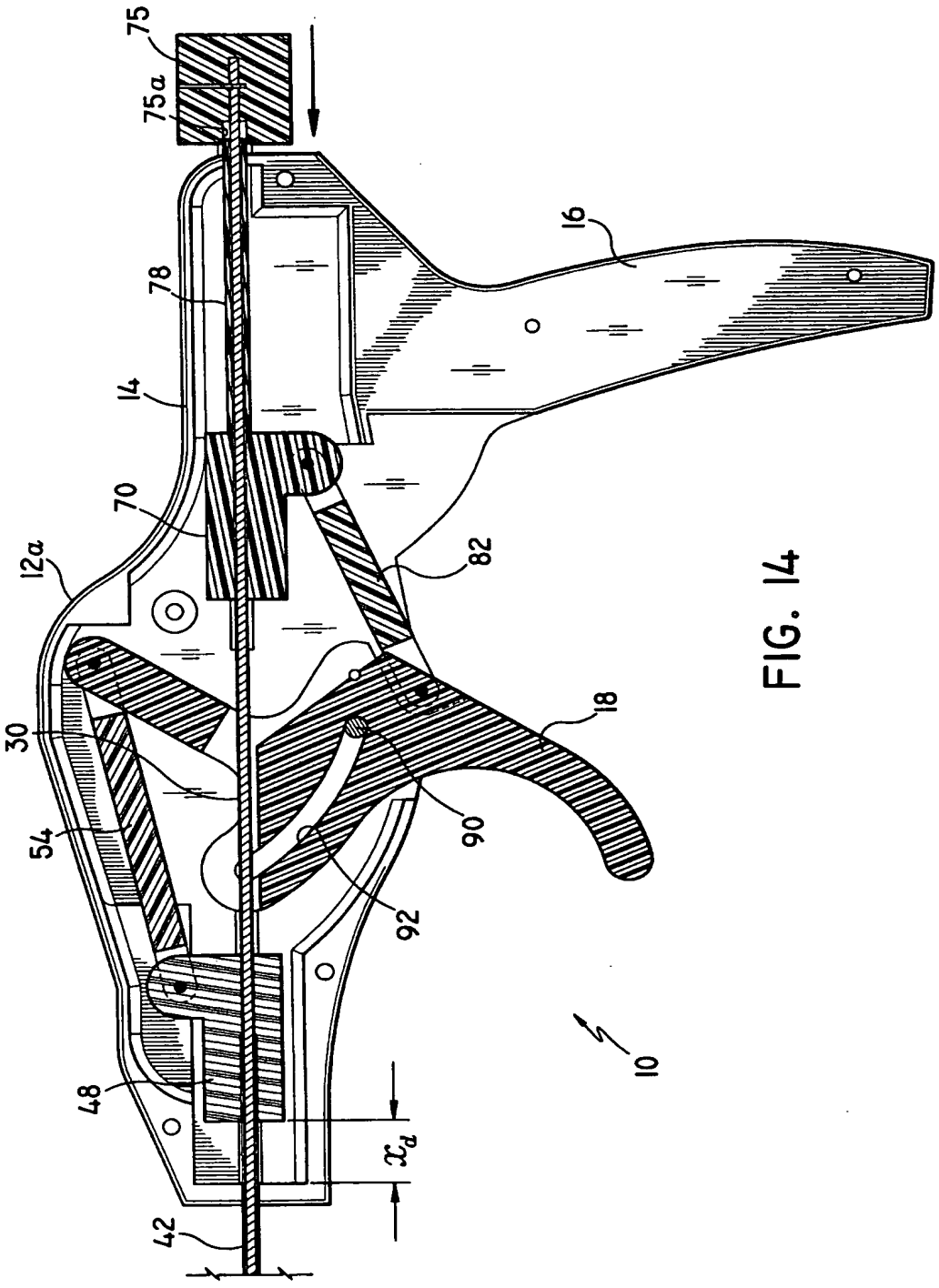

FIG. 14

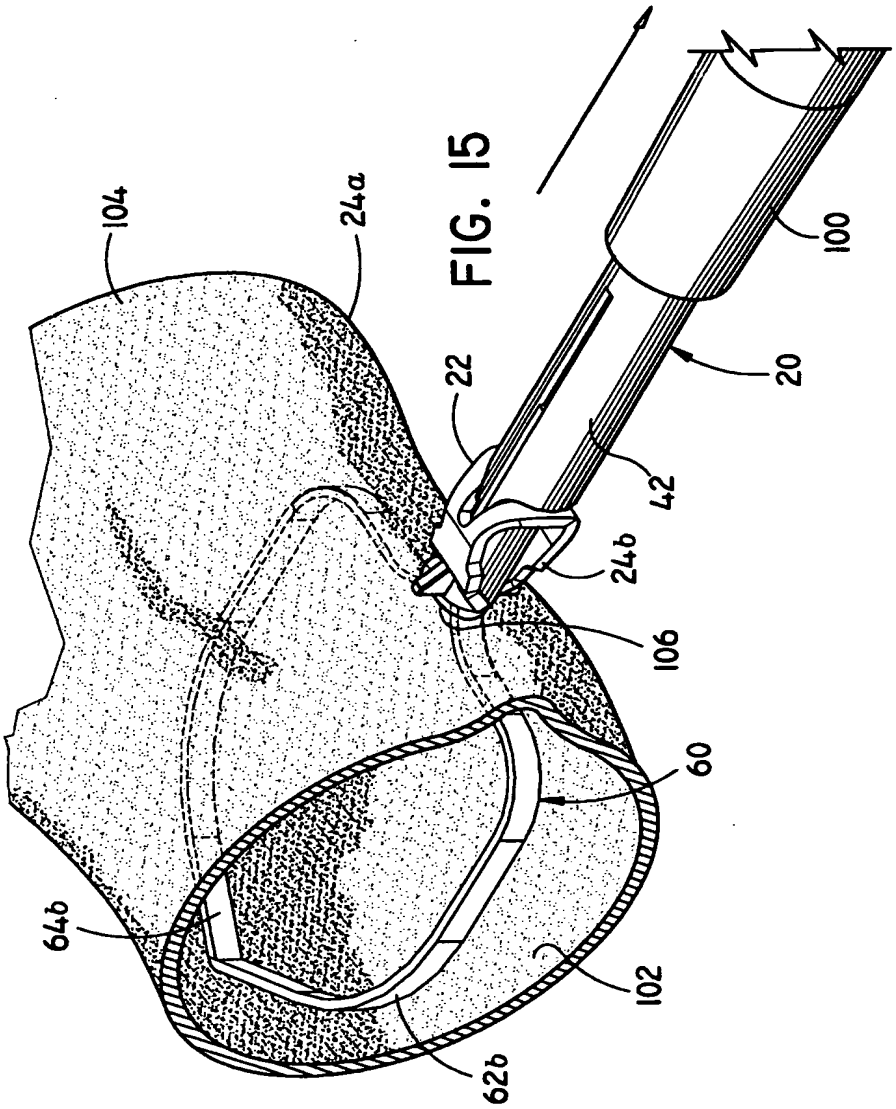

FIG. 15

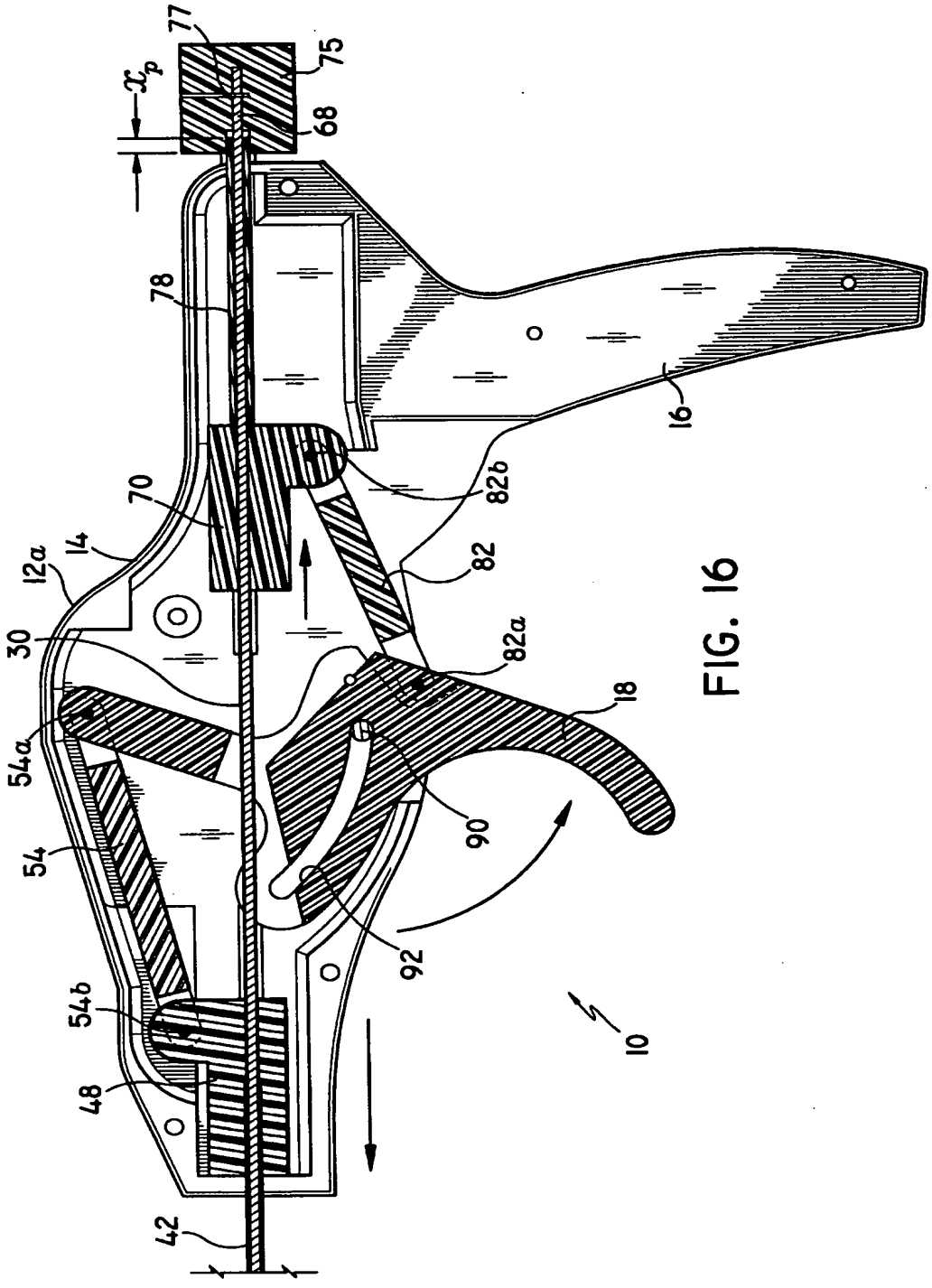

FIG. 16

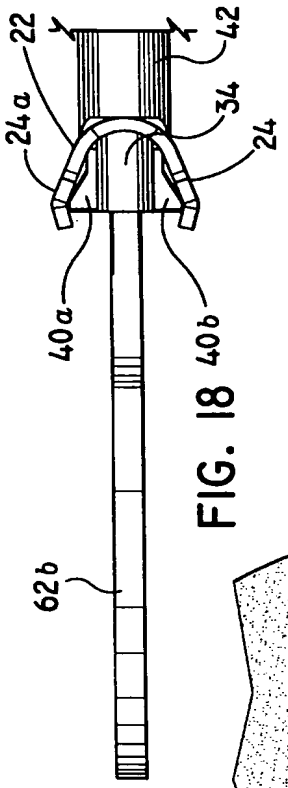
22
42
24a
34
24
40a
40b
62b

FIG. 18

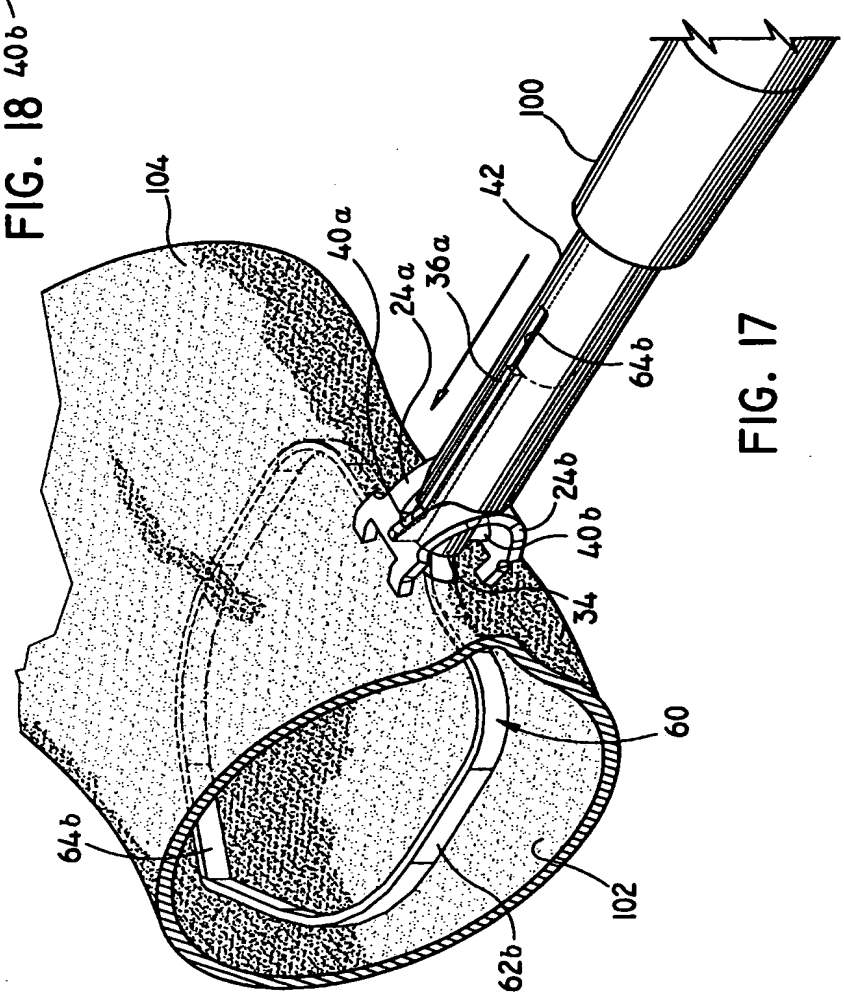
100
104
42
40a
36a
24a
64b
24b
40b
34
60
64b
102
62b

FIG. 17

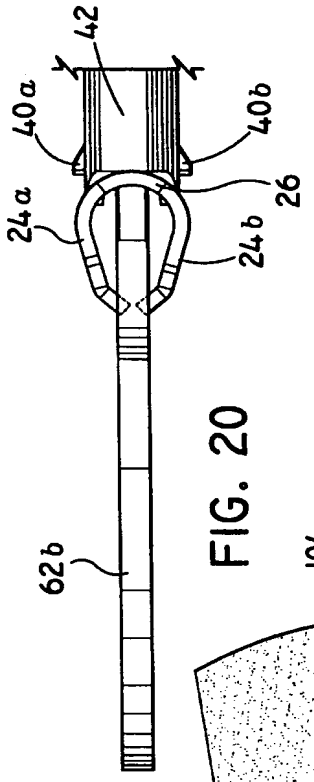
42
40a
40b
26
24a
24b
62b

FIG. 20

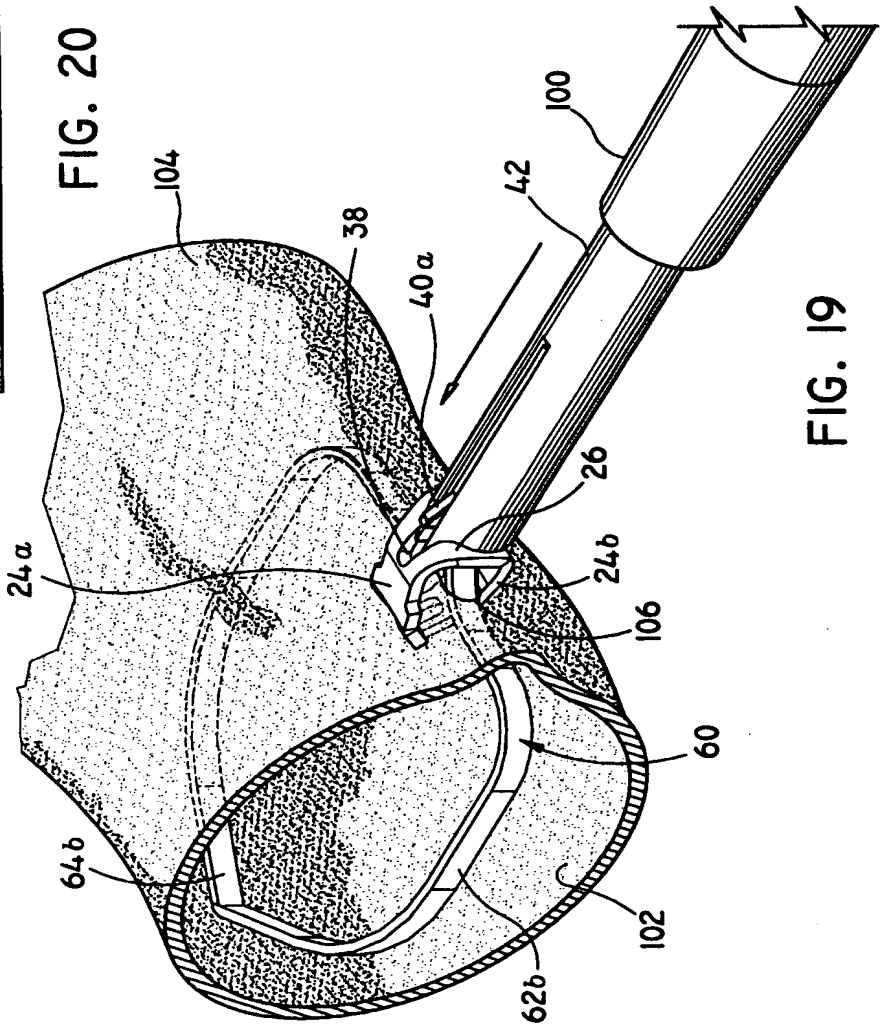
100
42
104
38
40a
26
24a
24b
106
60
64b
102
62b

FIG. 19

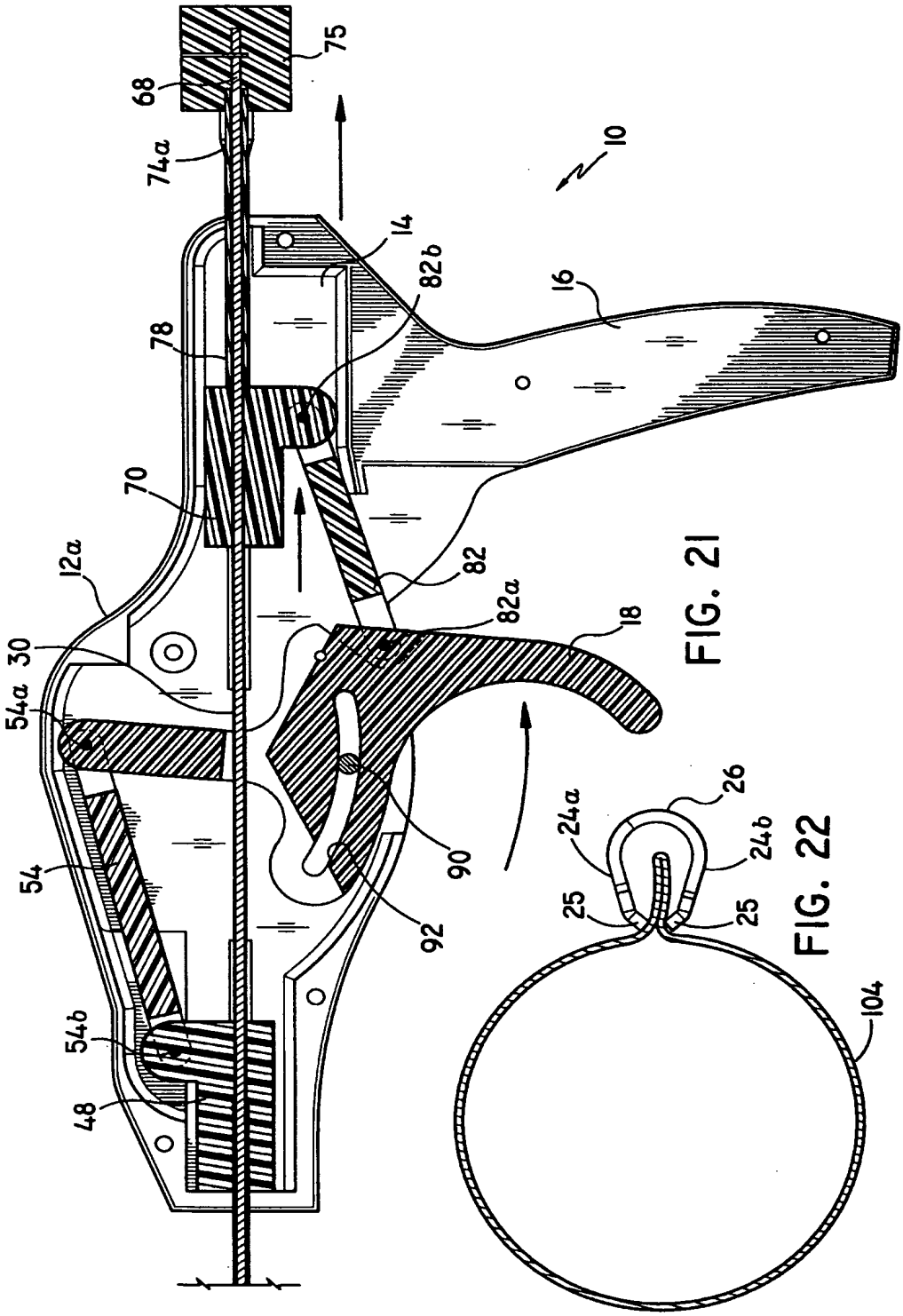
75
68
74a
10
14
82b
16
78
70
12a
82
82a
18
30
54a
54
90
92
54b
48
24a
26
24b
25
25
104

FIG. 21

FIG. 22

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(54) Apparatus and method for vascular hole closure

(57) An apparatus and method are disclosed for applying a surgical clip (22) to an exterior wall of a blood vessel (104) to at least partially close a hole (106) formed therein. The apparatus includes a handle portion, an elongated body (20) extending distally from the handle portion and dimensioned to extend through a hole in the wall of a blood vessel, and a collapsible locator (60) associated with a distal end portion of the elongated body (20) and mounted for movement between a collapsed position and an expanded deployed position. The locator (60) is adapted to expand within an interior lumen of the blood vessel to maintain the distal end portion of the elongated body in a desired location with respect to the hole (106) in blood vessel wall such that a surgical clip (22) releasably supported adjacent the distal end portion of the elongated body can be applied to the exterior wall of the blood vessel (104) to close the hole (106) formed therein.

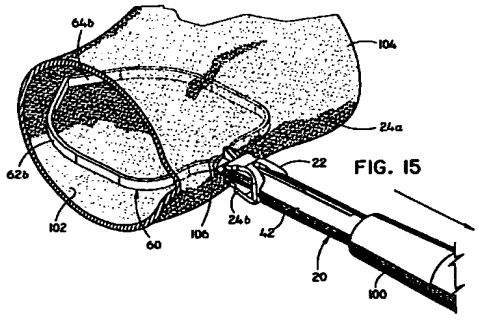

FIG. 15

EP 0 774 237 A3

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 96 11 6909

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X	US 5 304 184 A (HATHAWAY DAVID ET AL) 19 April 1994 * column 3, line 48 - column 5, line 27; figures 1-5 *	16	A61B17/00 A61B17/128 A61B17/122
A		1,2,17	

X	WO 92 22252 A (ASHRIDGE AG) 23 December 1992	16	
A	* page 5, line 8 - page 5, line 29; figures 6-8 *	1,2,17	

A	US 5 242 456 A (NASH JOHN ET AL) 7 September 1993 * abstract; figure 20 *	1,16,17	

D,A	US 4 929 240 A (KIRSCH WOLFF M ET AL) 29 May 1990 * column 4, line 59 - column 5, line 42; figure 7 *	1,16,17	

			TECHNICAL FIELDS SEARCHED (Int.Cl.6)
			A61B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
BERLIN	7 May 1997	Jameson, P

CATEGORY OF CITED DOCUMENTS

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